ANTHRAX VACCINE ADVERSE REACTIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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ANTHRAX VACCINE ADVERSE REACTIONS

WEDNESDAY, JULY 21, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Souder, Terry, Schakowsky, and Tierney.

Also present: Representative Gilman.

Staff present: Lawrence Halloran, staff director and counsel; Robert Newman, professional staff member; Jason Chung, clerk; Bill Ochs, intern; David Rapallo, minority counsel, and Earley Green, minority staff assistant.

Mr. SHAYS. Good morning and welcome.

In April, we heard testimony from three members of the Michigan Air National Guard unit who suffered serious health effects after receiving the anthrax vaccine. Their personal stories conveyed the concerns of many men and women in our armed forces about the long-term safety of a little-used vaccine.

Their testimony also raised important questions about the willingness and ability of the Department of Defense, DOD, anthrax vaccine immunization program [AVIP], to acknowledge the side effects and adverse reactions caused by the vaccine. We address those questions today.

All vaccines cause reactions. In fact, that is their purpose, to stimulate a response from the immune system. But in doing so, vaccines also cause in some people varying degrees of negative health consequences ranging from a sore arm to potentially fatal hyper-sensitive or allergic reactions.

Due to its composition and the number of inoculations required, the anthrax vaccine causes local and systemic reactions at what DOD once called problematic rates. Some reactions may become apparent as vaccine usage expands from a few hundred people each year to 2.5 million members of the military.

To capture the true rate of health effects and to detect unexpected reaction trends, AVIP surveillance systems must be sensitive and receptive to adverse events reports.

Are they?

Military doctors must be advocates for their patients, not purveyors of program orthodoxy.

Are they?

Those receiving the vaccine must be free to seek medical advice and pursue suspected associations between the vaccine and their illnesses without fear of retribution or ostracism.

Are they?

Many think not. Service members report massive vaccination sessions during which little medical information is imparted, little medical history elicited, and no questions or doubts are tolerated. They describe a program that often fails to offer legitimate medical exemptions from the inoculation, glosses over potential side effects, and aggressively denies any attempt to link adverse events with the vaccine.

Others, like the Michigan National Guard members who testified in April and those who are here today, face intimidating official resistance when they ask whether the vaccine may be a cause of their medical problems. As a result, the number of AVIP-related cases in the Food and Drug Administration [FDA], Adverse Event Reporting System, referred to as VAERS, seems purposefully and implausibly low.

Despite the under-reporting inherent in a passive surveillance system, VAERS is a tool DOD could use to gather important data about the impact of the AVIP on troop health and readiness. Instead, illnesses subsequent to vaccination are attributed to coincidence or pre-existing conditions in the interest of protecting the anthrax program rather than the patient.

The practice of medicine, not public relations, should be driving the adverse event reporting process. Whether the adverse reaction rate is two-tenths of 1 percent or 21 percent, DOD has an obligation, a profound obligation, to protect those in the military force, in the force made ill by this force protection program.

If women suffer adverse health effects at twice the rate of men, DOD has an obligation to acknowledge and ameliorate those effects. If a pure vaccine or fewer than six inoculations would provide protection while causing fewer reactions, DOD again an obligation to pursue FDA approval of those options.

We are going to proceed from the premise all our witnesses share one interest, the health and safety of those in service to the Nation. That is going to be our premise.

Thank you all for your time and your testimony this morning. And again, welcome.

[The prepared statement of Hon. Christopher Shays follows:]

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS

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Statement of Rep. Christopher Shays

July 21, 1999

In April, we heard testimony from three members of a Michigan Air National Guard unit who suffered serious health effects after receiving the anthrax vaccine. Their personal stories conveyed the concerns of many men and women in our armed forces about the long- term safety of a little-used vaccine.

Their testimony also raised important questions about the willingness and ability of the Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP) to acknowledge the side effects and adverse reactions caused by the vaccine. We address those questions today.

All vaccines cause reactions. In fact, that is their purpose: to stimulate a response from the immune system. But in doing so, vaccines also cause in some people varying degrees of negative health consequences, ranging from a sore arm to potentially fatal hypersensitive or allergic reactions.

Due to its composition and the number of inoculations required, the anthrax vaccine causes local and systemic reactions at what DoD once called problematic rates. Some reactions may only become apparent as vaccine usage expands from a few hundred people each year to 2.5 million members of the military.

To capture the true rate of health effects, and to detect unexpected reaction trends, AVIP surveillance systems must be sensitive and receptive to adverse event reports. Are they?

Military doctors must be advocates for their patients, not purveyors of program orthodoxy. Are they?

Those receiving the vaccine must be free to seek medical advice and pursue suspected associations between the vaccine and their illnesses without fear of retribution or ostracism. Are they?

Many think not.

Service members report mass vaccination sessions during which little medical information is imparted, little medical history elicited and no questions or doubts are tolerated. They describe a

program that often fails to offer legitimate medical exemptions from the inoculation, glosses over potential side-effects, and aggressively denies any attempt to link adverse events with the vaccine.

Others, like the Michigan Air National Guard members who testified in April, and those we will hear today, face intimidating official resistance when they ask whether the vaccine might be a cause of their medical problems.

As a result, the number of AVIP-related cases in the Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS) seems purposefully, and implausibly, low. Despite the under-reporting inherent in a passive surveillance system, VAERS is a tool DoD could use to gather important data about the impact of the AVIP on troop health and readiness. Instead, illnesses subsequent to vaccination are attributed to coincidence or pre-existing conditions in the interests of protecting the anthrax program rather than the patient.

The practice of medicine, not public relations, should be driving the adverse event reporting process. Whether the adverse reaction rate is two tenths of one percent or 21 percent, DoD has an obligation to protect those in the force made ill by this force protection program. If women suffer adverse health effects at twice the rate of men, DoD has an obligation to acknowledge and ameliorate those effects. If a purer vaccine, or fewer than six inoculations, would provide protection while causing fewer reactions, DoD has an obligation to pursue FDA approval of those options.

We proceed from the premise all our witnesses share one interest: the health and safety of those in service to the nation. Thank you all for your time and your testimony this morning. Welcome.

Mr. SHAYS. At this time, I would ask if Mr. Tierney has any opening statement he would like to make for the record.

Mr. TIERNEY. I do not. Thank you.

Mr. SHAYS. Thank you, Mr. Tierney.

So at this time, let me first get some business out of the way. And that would be to ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record, and the record remain open for 3 days for that purpose.

Without objection, so ordered.

And I ask further unanimous consent that all witnesses be permitted to include their written statements in the record. And without objection, so ordered.

And I am further going to ask unanimous consent to insert in the hearing the record written statements from Randy Martin-Allaire, Roberta Groll, and David Churchill, members of the Michigan Air National Guard, who testified before the subcommittee in April. And we asked them to update us on their health and their efforts to determine whether the anthrax vaccine played a role in their illnesses.

I am happy to report their health has improved somewhat, but they remain very frustrated and disappointed over the DOD response to their plight.

And without objection, we will put that in the record as well.

Now we will welcome our first panel. We have five witnesses who will testify. Captain Michelle Piel, U.S. Air Force; Lieutenant Richard Rovet, U.S. Air Force.

Captain Piel is from Stevensville, MD, and Lieutenant Rovet is from Dover, DE.

Now we also have Sergeant Robert Soska, U.S. Air Force—U.S. Army, I'm sorry—Fort Stewart—excuse me, Sergeant—and Captain John Richter, U.S. Air Force, Annapolis, MD, and Lieutenant Colonel John Jensen, Great Falls, MT, and he is with the Montana Air National Guard.

We welcome all of you here today, and as is our practice, we swear in our witnesses, this being an investigative committee. We do it for Members of Congress as well when they testify before us. And we would welcome you to stand and we will administer the oath. If you would raise your right arms please.

[Witnesses sworn.]

Mr. SHAYS. Thank you. For the record, all five have responded in the affirmative.

And I think we have you seated according to the way we are going to proceed. We will start with you, Captain Piel.

And what we do is, we have the light on for, it will be on for 5 minutes. We will roll it over another 5 minutes, and certainly ask you to finish before that second roll-over is done. And do know that your record will be—your full statement will be in the record if you care to leave out some parts.

Capt. PIEL. Yes, sir.

Mr. SHAYS. I am also going to say to all of you before you testify, I have served in Congress 11 years, and I know for a fact that military personnel do not like to come before Congress. This is not something you look forward to. It is not something you enjoy. And

you do it with some recognition that you put your careers in some jeopardy, even when we say you don't.

And we certainly keep track of our witnesses and do our best to make sure they are treated fairly as they complete their career. But we know you are here at our request, and we thank you for being here.

Captain Piel.

STATEMENTS OF CAPTAIN MICHELE L. PIEL, U.S. AIR FORCE, STEVENSVILLE, MD; LIEUTENANT RICHARD ROVET, U.S. AIR FORCE, DOVER, DE; SERGEANT ROBERT SOSKA, U.S. ARMY, FORT STEWART, GA; CAPTAIN JON RICHTER, U.S. AIR FORCE, ANNAPOLIS, MD; AND LIEUTENANT COLONEL JOHN JENSEN, GREAT FALLS, MT

Capt. PIEL. Good morning, Mr. Chairman and members of the committee.

Mr. SHAYS. I am sorry, Captain, I am going ask you to move that mic a little closer to you. If it kind of gets in the way, you could lift it up a speck if you wanted. Is it all right? Can you——

Capt. PIEL. It is fine.

Mr. SHAYS. OK. That is better. We hear your voice better. Thank you.

Capt. PIEL. First of all, I would like to thank you for interest in the anthrax immunization program and also for requesting my testimony today. The views which I will express will be my own and in no way reflect those of the Department of Defense, the Air Force, or my superior officers.

I am a C–5 pilot at Dover Air Force Base, DE. I hold the position of aircraft commander and I am also a flight commander within my squadron. My whole life I have wanted to fly and serve my country. And as a graduate of the Air Force Academy, I was able to achieve both.

I have had a very rewarding 13-year career, and I am grateful to everyone who has helped me along the way. Today I am going to talk to you about my experiences.

In October, I was healthy and flying operational missions. I became ill the first of November and then again in December following my first and second anthrax immunizations. On October 1st—excuse me, on October 21st I received my first immunization from Lot 030. It wasn't until weeks later, while I was flying a mission in support of Hurricane Mitch relief efforts, that I became ill.

The right side of my head filled up with fluid while I was on a return leg to Pope Air Force Base. After landing, the flight surgeon grounded me. I had otitis media, which is an inflammation, or an infection of the middle ear. And I also had a very bad head cold.

These symptoms persisted for 3 weeks. My doctor back at Dover and I discussed whether or not I should receive an immunization at this time, and we felt that it would be improper and that we should wait until I had fully recovered.

On November 30, I went to the flight surgeon's office to get put back on flying status. He returned me to flying status and I went straight to the immunization clinic to get my next vaccination. Following the second vaccination, I felt fine directly afterward. But later that afternoon, I began to feel very tired.

I went home, straight to bed, and I did not wake up until the next morning. I awoke feeling very ill, and I returned to the doctor. The doctor was very surprised at my condition, the change from the day before to that day. And, of course, I went back on non-flying status.

And he asked me, what did you do differently between yesterday and today? And I told him, the only thing that I could think of was that I had my anthrax immunization.

In December, I had dizziness to the point it affected everything that I did. I could not drive; I could not read a page of paper; I could not concentrate. At the lowest point, my vision blurred, which is very critical to me because it affects my career as a pilot.

During this time, the diagnosis was viral labrynthitis, which is an inflammation of the inner ear, and it can cause dizziness because it affects your balance system.

I do not know exactly what was happening to me, but the doctors assured me that within 4 to 6 weeks I would recover from viral labrynthitis. Well that did not happen.

I saw many doctors over the course of the next 6 months, and nobody could, I don't feel, adequately address my problem. It wasn't until I began going to Walter Reed at the decision of my wing commander, Colonel Greider, that I began to get my problems recorded in my medical records and receive blood tests, which would help try to determine what was causing my symptoms. I have had a very slow recovery, with periods of regression, but I strived to maintain a positive mental attitude and recover my flying status and career.

I would like to talk to you know about deferral criteria. The only information I was given at the time of the shot was the trifold pamphlet, which we are all familiar with, what every service member should know.

Although I did not have deferral, I have not received any shots since November, during the first few months of my illness, doctors asked me if I would like to continue my anthrax immunizations. They even suggested taking incremental doses to see what would happen.

Because I was still ill, I felt that this was unwise, and no one pushed the issue. At this point, I was in a gray area.

There was no diagnosis, and yet I was still ill. I valued my career, but I also couldn't afford to jeopardize my health, because without my health, I have no career.

No I will talk about the VAERS system, Vaccine Adverse Event Reporting System, and how that was communicated to me.

The doctors did not file a VAERS report on me. It wasn't until May that I learned about the VAERS system. At that point, I felt it would be wise for my doctor and I to file it together because I wanted it to be accurate.

When I went to the chief flight surgeon at Dover Air Force Base, my request met reluctance. I thought that any loss of duty over 24 hours should be reported in VAERS. But he did not agree that I had had a reaction.

So then I asked him what he did think was reportable under VAERS. And he listed things like difficulty breathing, rash, sweat-

ing, fever, nodules, and anaphylactic shock. My case clearly did not fall within those criteria.

I asked him, what about effects on the immune system and the nervous system, because I felt that maybe that was happening to me. But I had no answer to that question.

At this point, I was confused because I was too sick to fly and I was too sick to get another shot. But I wasn't sick enough or in the right ways for it to be reportable.

There would be no data collection at Dover Air Force Base if it wasn't for the fact that Lieutenant Rovet pursued the issue. He followed up on all of our cases; he tried to help us out. And all of his efforts were met with resistance and discouragement.

However, when we reported our symptoms to our commanders, it went up the chain of command to Colonel Greider. And when our wing commander, Colonel Felix Greider, found out what was happening at his Air Force base, he took the health of his wing very seriously. That was when we had the series of briefings, and we got a lot of attention at our base, to say the least.

The information that we got in the first briefings wasn't adequate. And, dissatisfied, Colonel Greider decided to call a timeout until our health issues could be addressed properly. This is important to the collection of data because before he called the timeout, there was no VAERS data from Dover Air Force Base. There was no collection or reporting.

No one knew what was happening outside of our base.

I would also like to say that as far as diagnosis and treatment within the medical community at Dover, I did not get directed to Walter Reed. I got directed to from Colonel Greider and put in touch with the immunology clinic, where they began to actually record my symptoms in my medical records and give me blood tests to try to determine what may have, what may be wrong with me, besides the fact that I had an ear infection.

What they did find was that I had a positive ANA marker, which is an auto-immune disorder, an indication of that. It is not that I have been diagnosed with a specific disease; however, my symptoms are consistent with having immune system problems.

The last few months I have felt some improvement; however, the fatigue is affecting how I live, and it is also affecting whether or not I am capable of flying. I also have periodic returns of the dizziness, which I also cannot fly in that condition. And I also have headaches and other things which affect me to a lesser degree.

I missed several weeks of work in January; I missed all of work in December; I missed 3 weeks of work in November. I missed a lot of work. And none of this was reported.

However, now it is. An IG complaint was filed at Dover because when the VAERS reports were finally filed, they were filed inaccurately. The most egregious error is that they marked that the reports were self-filed, indicating that I and the others that they filed reports on had filed it ourselves, when, indeed, we had nothing—I had nothing to do with my VAERS form. I saw it later, and I noticed that there were some inaccuracies on the form.

What's happened since then is we have gone back and corrected what is wrong with those forms. So at least adequate information is making it to the FDA right now.

VAERS is important because it is our only way of tracking this illness or I should say adverse events that may be connected to the vaccine. I realize that a diagnosis and treatment in cases of unexplained illnesses are complex. And I know that the doctors had a very difficult time, and they did not, or were not, fully prepared to take care of me at the time.

But right now I am receiving excellent medical care. I do not know the cause or impact of the ANA antibodies in my blood, but my focus is on flying and getting healthy. I want my whole life back.

I have testified today at your invitation because I believe our military's health is critical to our Nation's war-fighting readiness.

That concludes my statement. Do you have any questions?

[The prepared statement of Capt. Piel follows:]

Anthrax Vaccination Immunization Program (AVIP)

House Government Reform and Oversight Committee Hearings

Subcommittee on National Security, Veterans Affairs, and International Relations

Chairman Shays Presiding

21 July 99

Written Statement by: Captain Michelle L. Piel

Mr. Chairman and members of the committee, I thank you for your continued interest in the Anthrax Vaccination Immunization Program (AVIP) and for requesting that I share my personal experience with you. Please note that any opinions I express are my own and in no way reflect the opinions of the Air Force or my superiors.

I am a C-5 Galaxy pilot stationed at Dover AFB, DE. All my life I've wanted to fly and serve my country to the best of my ability. As an Air Force Academy graduate, I've had every opportunity to achieve both. I've enjoyed a rewarding career serving with the finest people I will ever know. I owe a debt of gratitude to everyone who has helped me along the way over the past 13 years. I would like to take the opportunity to express my sincere appreciation to my Wing Commander who found quality medical care for me. If it weren't for the fact that he temporarily suspended the anthrax program at Dover AFB, I would still be lost in our military medical system. My desires are simple: to regain my health and return to flying.

Experiences with the AVIP. Last October, I was healthy and flying operational missions. I first became ill in November and then again in December following my first and second anthrax vaccinations. Presently I am on indefinite DNIF (duty not including flying) status. Let me briefly summarize the events which led up to my decline in health.

My first anthrax immunization from lot 030 was on 21 Oct 98. My arm went numb for about 20 min., but others felt the same so I wasn't concerned. Weeks later, while flying a return leg from Honduras supporting Hurricane Mitch, the right side of my head filled up with fluid. It was as if a faucet were turned on inside my head. After landing at Pope AFB, North Carolina, the flight surgeon grounded me on sight for a head cold and middle ear infection. Within days, the fluid building up in my ear caused dizziness. When I returned to Dover, I was told to delay my second anthrax vaccination because of the

antibiotic and the infection. I recovered in three weeks.

On the morning of 30 Nov 98 my doctor returned me to flying status and I went straight to the clinic for my second anthrax injection (lot 030). I had the same numbness in my arm which subsided after 20 min. By afternoon, I began to feel excessively tired and fatigued. I went home and slept the remainder of the day. When I woke up the next day, I did not feel well. My body was very tired although I had slept for over 12 hours and my head was reeling. I returned to the doctor. He was very surprised at the change in my condition. He asked, "What did you do differently between yesterday and today?" The only difference was the anthrax immunization.

My doctor then referred me to an ENT (ear, nose, throat specialist). The ENT diagnosed viral labrynthitis, which is an inflammation of the inner ear. He expected me to recover in 4-6 weeks. Throughout December my symptoms became worse. The dizziness progressed to the point that I could not drive, read a page of paper, or concentrate. I was so tired I slept most of the day and so nauseous I barely ate. At my lowest point, my vision blurred. I could not work in December at all. I relied upon my husband and my mother to take care of me. The doctors told me it would take time for me to get better.

I saw three different ENT's—including one private ENT in January. They agreed with the diagnosis, viral labrynthitis and told me to be patient. During this period my symptoms were dizziness, periodic headaches, unusual fatigue, and joint aches. I also missed several weeks worth of duty as a flight commander due to my symptoms.

February brought slight improvement regarding the dizziness. Unfortunately, I contracted a cold and this worsened my symptoms. I had several colds throughout the spring and they were much harder on my body than I had normally experienced. During March, a neurologist described my "viral labrynthitis" as "not behaving correctly". 12 different doctors, including civilians at my own expense, had no explanations for my ongoing condition. In April I had a left breast lumpectomy which caused a my symptoms to increase.

At the end of May, my wing commander put me in contact with the Immunology Clinic at Walter Reed Army Medical Center. The doctors promptly recorded my symptoms in my medical records and sent me for blood tests. My blood tested positive for antinuclear antibodies (ANA) which are a marker for autoimmune disorders. Although I did not have a specific disease, my symptoms were consistent with immune system problems. Due to this, the doctors at Walter Reed recommended a waiver from immunizations.

The last few months I have felt some improvement in my condition. The dizziness has become less frequent. However, the fatigue is like living at midnight and remains a major factor in how I live. I have also continued to experience joint pain, periodic ear aches, and headaches. There is no way that I know of to prove that the anthrax vaccine caused any of this. All I can tell you is that I became uncharacteristically ill after I started taking the anthrax shots. It has taken 12 doctors and 8 months for me to finally find any reason for my symptoms.

My recovery is slow, and I continue to have periods of regression. However, I maintain a positive mental attitude and strive to get healthy again in the long run.

Effectiveness of AVIP in communicating deferral criteria. The pamphlet entitled, "What Every Service Member Should Know About the Anthrax Vaccine" was the only information given at the time of my immunizations. Pregnancy was the only deferral criteria mentioned. The pamphlet did say to inform your health care provider before taking the shot if you have any medical condition or are taking medication. Because of my illness, on 13 Nov my doctor decided that I should wait to take my 2nd shot until I had fully recovered.

Since Nov, I received no further shots due to my illness. During the first several months I was sick, the doctors often asked me if I would submit to continuing anthrax immunizations. They even suggested taking incremental doses to see what would happen. Because I still felt ill, I did not think it wise to try more vaccine. No one pushed the issue. But I wondered if I would get a deferral. I realized that I was living in a gray area. If my doctors never found a diagnosis, where did that leave me? I valued my military career, but I could not afford to further jeopardize my health. I clearly remembered how helpless I was in December.

Even now, I still do not have a waiver.

Communicating Vaccine Adverse Event Reporting System (VAERS) standards and procedures. When I became sick for unexplained reasons after the 2nd anthrax shot, I think the doctors did not consider VAERS because my symptoms did not fall within traditionally reported reaction criteria. This is a major reason why adverse events from the anthrax vaccine are underreported. The reports are considered only for "reactions" and not used to record "adverse events." My doctor couldn't prove my symptoms were caused by a reaction to the vaccine and so in his judgement my case wasn't reportable.

In May, I became aware of VAERS (www.fda.gov/cber/vaers/what.htm). I knew I could file a report on my own but I believed that my doctor and I should file one together. My request met reluctance. I thought that adverse events causing a loss of duty time over 24 hours were reportable. The chief flight surgeon did not agree that I'd had a "reaction" to the vaccine. When I asked what he considered reportable, he gave me examples such as difficulty breathing, rashes, sweating, fever, nodules, and anaphylactic shock. All of these are classic allergic reactions. My case did not fall within those criteria. So I asked about whether effects on the immune or nervous systems were reportable. I did not get an answer to this question.

It didn't make sense to me. I was too sick to fly. I was too sick to get another shot. But my illness wasn't reportable on a VAERS form?

Collecting Adverse Reaction Data. Only one person stepped forward as a patient advocate, Lieutenant Rich Rovet. As Dover AFB's Health Care Integrator, he followed up on my case and others. He saw a trend and he believed it was his duty to try to help the sick. His efforts were met with resistance and discouragement from within Dover's medical community, but he held a steady course and collected data. He raised health issues up the chain of command until they reached the very top. We had an apparent health crisis at Dover and when our wing commander found out about it, he took it seriously.

The wing commander conducted a thorough review, invited experts to our base to brief us on the AVIP, and held their feet to the fire. Unfortunately, the speakers were ill prepared to deal with our medical questions. Dissatisfied, the wing commander called a "time out". This is important because up until May 5, 1999 no VAERS were filed and no data officially existed.

The repercussions from the program's suspension were tremendous. Everyone I spoke to at Dover AFB recognized that our wing commander sacrificed his career for us. After the fallout, Dover medical personnel filed VAERS on our symptoms. However, they completed forms without patients' inputs and marked "self-filed" instead of "filed by healthcare provider". One of the patients filed an Inspector General (IG) complaint about this oversight. On July 14th, I went to Military Public Health and corrected inaccuracies on the form. Finally, the right information was reaching the FDA.

Diagnosing and Treating Adverse Reactions. It took 6 months to reach the right, highly specialized doctors to begin to diagnose my immune system problems. During this time, I related my difficulties of extreme fatigue, joint pain, and dizziness numerous times. However, very limited information (sometimes no record at all) made it into my medical records. I felt discouraged by doctors' comments such as: "you're depressed", "maybe you just want to have babies", "malingerer", "perhaps you need counseling". I recognized that these remarks weren't diagnosis; they were labels. I figured that they didn't know how to fix what was wrong with me, so they lost faith and blamed me for my illness. This pattern happens in cases of unexplained illnesses. I too became frustrated that the doctors couldn't cure me. At times, I lost faith in them as well.

I had many referrals, but little help in diagnosing and treating my illness nor medically addressing possible adverse affects of anthrax vaccine. Things changed when my wing commander put me in contact with doctors at Walter Reed Army Medical Center on 24 May 99. They fully documented my case and sent me for a battery of blood tests. The results were interesting. I tested positive for anti-nuclear antibodies (ANA) which indicated an autoimmune reaction in my blood. Finally, I had somewhat of an answer.

Diagnosis and treatment in the case of unexplained illnesses are complex. I believe that if it weren't for the dedication of Lt. Rovet and leadership of my wing commander, I wouldn't have any answers at all. Although I don't know the exact cause and impact of these antibodies yet, my focus is on getting healthy. I want my whole life back.

I have testified today at your invitation because I firmly believe that our military's health is critical to our nation's warfighting readiness. This concludes my statement. I would be happy to answer any questions you may have.

Mr. SHAYS. Thank you. Captain, we are going to have everyone testify, and then we are going to be asking you questions. And your testimony is very important. I didn't want to interrupt it, but I know that Mr. Gilman, the senior on this full committee, would be chairman if he chose to, but he is chairman of the national—international committee.

If the other members don't mind, I would welcome you to give a statement.

Mr. GILMAN. Thank you, Mr. Chairman. Thank you for allowing me to intervene. I have to go back to the floor to conduct our hearing on our major bill that's before the house, and I was very much interested in Captain Piel's testimony, and I have been glancing through the other testimony. And I hope to get back to the committee at the earliest possible opportunity.

I want to thank you, Chairman Shays, for convening this hearing today as part of your series of ongoing hearings related to the Department of Defense anthrax vaccination program. I think it is an important hearing.

I recall serving under subcommittee in the last Congress, where we held a series of very productive hearings on the subject of the Gulf War Syndrome. Those hearings led to much-need legislation, providing valuable assistance to our Persian Gulf war veterans and their families. And hopefully, these series of hearings on anthrax will do the same.

While I no longer serve on your subcommittee, I have followed your previous three hearings with great interest. And after reviewing the background material from these hearings, I find myself with more questions when I finished than before we started.

It appears that this vaccination program was initiated in a hasty manner, before a proper amount of research on the effectiveness and safety of the vaccine was completed.

Even more distressing has been the reports of deliberate downplaying of adverse reactions among our military personnel who have received the shots to date. These reports, of course, are all too familiar for those of us who investigated the Gulf War Syndrome issue.

Then as now, there was the all-too-frequent case of commanders who are more interested with following the official public relations message rather than being concerned with the welfare of the personnel under their command.

Mr. Chairman, these hearings are important, as they help keep the Department of Defense focused on an uncomfortable issue and remind both officials at the Pentagon and the members of the public of Congress' determination to fully address this subject.

Mr. Chairman, I commend you for your efforts and look forward to today's testimony in our ongoing investigation.

Thank you, Mr. Chairman.

Mr. SHAYS. Thank you, Mr. Chairman. You need to get back to that floor. I would just like to, before calling Mr.—Lieutenant Rovet, just to acknowledge the presence of Janice Schakowsky. I don't know if you have a statement, but she has been a very active member of the committee, and a very helpful one, besides Mr. Tierney. And also, we have Lee Terry, who has been very active on

the committee as well as the vice chairman of the committee, Mark Souder.

Do any of you have any statement you would like to make.

[All nod in negative.]

Mr. SHAYS. OK. Thank you, because that helps. We will get right back to our witnesses.

Lieutenant.

Lt. ROVET. Good morning, Mr. Chairman——

Mr. SHAYS. Good morning.

Lt. ROVET. And members of the subcommittee. Thank you for inviting us here today. It is an honor to appear before you on this important issue. But I must say at the onset that these are strictly from my perspective at Dover Air Force Base and don't reflect the views of the Air Force of the Department of Defense.

I am a veteran of 14 years of service. I come from a wide variety background in the Air Force. I was prior enlisted. I worked my way up through the ranks, and it is an honor to be a commissioned officer and serve in the Air Force.

And my job at Dover entails what we call health-care integrator. And in that capacity, what I do is clinical nursing, case management, and patient advocacy. All those are very important to me. One that came to the forefront with this issue is patient advocacy because you have to be a voice for someone when they don't feel like they are being heard.

And that is not a knock against the folks of the medical group or the Air Force at large. They are good people.

Some of the things we have seen at Dover at the onset were a reticence upon the medical community to touch this issue. It was viewed as let's say politically sensitive, professionally risky to veer off the line on this issue.

I, myself, felt that in the beginning, but once I saw people coming forward, I had some questions. And I voiced those to my superiors. And I was not quite comfortable with the answer, although I smartly saluted and about-faced and went back and did my job.

Next, I started hearing some rumblings, and more people came forward. Then it became a matter of core values, it became a matter of, well, you are a patient advocate, you need to start looking into this issue.

What I would like to do is just briefly outline for the committee some of the adverse reactions at Dover, what we have seen. So far, we have reported 30, but there will be 5 to 6 more within the next week. And it is fair to say, out of these 30, there are unexplained illnesses. That may not sit well with the public relations machine or whatever have you, but if they are not diagnosed, we have no answer to these peoples' question, then logic states that they are unexplained illnesses. These people are all being worked up for anthrax, possible anthrax reactions.

I also would like to say that the vast majority of people it seems can tolerate the vaccine, and this may be a vital link to force protection, but I think we need to hash out these problems here that weren't put up forth in the beginning, at the onset of this program.

OK, for individuals, we have—some of these are multi-symptoms that people may exhibit—6 report dizziness; 6 report ringing in their ears; 10 report joint pains; 3 report muscle pain; 3 report

memory impairment; 2 report constant fatigue; 3 report numbness and tingling in various parts of their body; 1 reports photosensitivity, which the lights in this room are probably bothering the individual right now; one reports having a miscarriage post-vaccination, although the individual did not know she was pregnant at the time.

One individual reports what they call having gray-outs. That is like a pre-seizure, or it is something that we just don't know. But he calls it a gray-out. One complains of swollen and painful testicles; two report cardiac problems; one reports chills and fever greater than 48 hours post-vaccination; three report rash, swelling, and nodule at the injectionsite; two report non-localized persistent rash; one reports hyperthyroidism.

Again, when we say report, these are bona fide medical workups. They do have hyperthyroidism.

OK, according to the anthrax vaccine insert, we have, right now, according to the rhetoric that is out there, two mild reactions, three moderate local reactions, and three systemic, characterized by chills, fever, lassitude, and malaise.

Mr. SHAYS. Excuse me for interrupting you. Just so I understand the testimony. You are saying what's reported is the official documentation of the effect of the anthrax vaccine at Dover? Is that what you are saying?

Lt. ROVET. It is not official yet, but according to the insert, if we were to apply what's in the package insert, and strictly this is my testimony, it is not the Air Force's, so it is not official yet. I am just saying, if we were to apply the package insert to what we have here right now, this most likely would be what we have. But it is not a confirmed, they are not confirmed reactions.

There is significant confusion in relation to these categories, and especially in regard to what constitutes systemic reaction. This I hope will be looked into further to seeing that these are things that were not originally thought through in the beginning as systemic reactions.

I would like to speak briefly about the medical cultural climate that we see. I speak about the reticence upon the medical community, and I am not painting wide brush across all of the medical community, but providers, medical providers, view this issue as politically sensitive and like to avoid it.

One clinical supervisor stated on July 15, 1999, my providers won't touch this. They want nothing to do with it.

Initially, patients were thought of as malingerers, liars, and hypochondriacs, that this is some sort of mass hysteria akin to the polio vaccine when it came out. I don't, I cannot see these honorable men and women coming forward all over the country making this up or having some massive psychosomatic illness.

Sir, this needs to be looked into for the health of our country, for the morale and welfare of our troops. There are too many questions that are left unanswered.

This vaccine was sold with a 28-year track record of safety and efficacy. Now we notice that they say we don't know the long-term effects. Things seem to be fluctuating daily, recantations of statements. It was given to veterinarians on a widely used basis. We found that is not true.

This is such a sensitive issue post Gulf war era. We have veterans who are still sick and dying across this country, and some are making the link to the vaccine. I am not doing that here, but I find it interesting that we have unanswered questions with that. We have similar complaints to Gulf war illness appearing all over this country, and yet, we don't have the foresight in some areas, and I am not finger-pointing, to know that this was going to come up?

I work in an emergency downtown. I moonlight in the evening. And I met an individual, a retired individual, who injured himself. And we got to talking afterwards. And he knew I worked in flight medicine.

He started to bring up the anthrax vaccine program. And I listened, and I told him that it is obviously a hot topic. He explained to me his symptoms that occurred a little bit close to 9 years ago, and he perfectly described another individual who is in this room today. Instead of using the word gray-out, he used the word "episode."

His wife was in tears, and they were afraid to—and I said, well you need to come forward and be evaluated. He goes, I am afraid I will lose my benefits.

Speaking of fear, all through the squadrons on base, people are afraid to come forward for they are going to lose their flying status and lose their career if they come forward. For every one individual that comes forward, there are three individuals that will not.

These are many unanswered questions, sir. I just hope that for the good of the country and the good of the morale of our volunteer force that we will find some answers soon and press on and get back to business.

Thank you, sir.

[The prepared statement of Lt. Rovet follows:]

STATEMENT ON ANTHRAX VACCINE ADVERSE EVENT REPORTING

RICHARD J. ROVET, LIEUTENANT, USAF

PREPARED FOR THE HOUSE OF REPRESENTATIVES

Committee on Government Reform

Subcommittee on National Security, Veterans Affairs and International Relations

21 Jul 99

INTRODUCTION

Mr. Chairman, It is truly an honor to appear before the subcommittee and participate in the investigation of the Anthrax Vaccine Adverse Event Reporting System and the events that have transpired at Dover Air Force Base during the past several months.

For over fourteen years I have faithfully served this great nation of ours in a variety of capacities and have worked my way through the ranks to become a commissioned officer. Currently I serve as the Health Care Integrator for the Flight Medicine Clinic at DAFB. My duties include Case Management, Patient Education, Clinical Nursing and Patient Advocacy.

*The following statements are strictly mine and should not be viewed as those of the USAF

POTENTIAL ANTHRAX ADVERSE REACTIONS AT DAFB

-To date thirty individuals have filed VARES reports in regards to the anthrax vaccine (five more

will be processed by next week)

--Six report dizziness

--Six report ringing in the ears

--Ten report joint pain

--Three report muscle pain

--Three report memory impairment

--Two report constant fatigue

--Three report numbness and tingling in various parts of their body

--One reports photosensitivity

--One reports having a miscarriage post vaccination (individual did not know she was pregnant at time of vaccination)

--One individual reports having "greyouts"

--One complains of swollen and painful testicle

--Two report cardiac problems

--One reports chills and fever >48 hours post vaccination

--Three report rash, swelling and nodule at injection site

--Two report non-localized persistent rash

--One reports hypothyroidism

-According to anthrax vaccine package insert we potentially have

--Two mild reactions

--Three moderate local reactions

--Three systemic as characterized by chills, fever, lassitude or malaise

-There is significant confusion in relation to these categories, especially in regards as to what constitutes a systemic reaction

CHALLENGES TO ANTHRAX ADVERSE EVENT REPORTING

THE MEDICAL CULTURAL CLIMATE

-Medical Providers see issue as "politically sensitive"

--Clinical supervisor stated on 15 Jul 99, "My providers won't touch this, they want nothing to do with this"

--To the best of my knowledge only three providers have received the vaccine out of our entire medical group.

-One physician stated that illnesses without concrete etiologies are frustrating to us

-- Currently we have **30 unexplained medical conditions** DAFB

PATIENTS VIEWED AS SUSPECT, NOT THE VACCINE

-Initially patients who reported their illnesses as potentially related to the anthrax vaccine were viewed as " malingerers", "whiners"," liars" and "hypochondriacs"

--One patient complaint was filed on this issue

-In some cases patients told that their potential adverse event is in no way related to the anthrax vaccination

--Simple logic dictates that if we know what isn't a reaction then we must have a good handle on what is!

-- 13 Jul 99 USAF Technical Sergeant was told, by a medical officer at Walter Reed, that his condition cannot possibly be related to the anthrax vaccine (this was stated prior to evaluation)

FEAR OF NEGATIVE IMPACT ON THEIR CAREER

Many officer and enlisted individuals are afraid to come forward for fear of damaging their careers

--Patients state that for every person that reports an adverse reaction there are 2-3 who are afraid to come forward

--Pilots fear that a medical "black-mark " in their record would eliminate them from their current duties and diminish their chances to fly in the future for a civilian airline

-If an individual is found to have an adverse reaction to the anthrax vaccine, as with many vaccines , they are not considered worldwide qualified for duty.

CONFUSION IN REPORTING PROCEDURES

-Original threshold was high for reporting

--Physicians were told to filter to complete VAERS and check provider box if they felt the patients' condition was related to an adverse reaction

--To date, no provider has checked the provider box on the VAERS

--Reporting threshold was lowered in late May early June timeframe

--Individuals were encouraged to come forward if they suspected an adverse reaction

-Many separate agencies are requesting information regarding anthrax adverse reactions and limited guidence is given

--FDA collects VAERS. They also would like additional medical information on certain patients

--Brooks Air Force Base epidemiologists are also requesting VAERS and additional patient data

--Walter Reed Immunology Dept, who is currently evaluating many of our patients is also requesting additional medical information

--Walter Reed and DAFB Medical Group have recently coordinated services for five individuals who originally reported adverse reactions. These patients are to be evaluated by a team of physicians at Walter Reed

-This has the potential for fragmentation of data and is confusing for the "front line" medical troop

-ANTHRAX ADVERSE EVENT REPORTING AND PATIENT EVALUATION SHOULD BE STANDARDIZED ACROSS THE DOD

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CONCLUSION

The Proud Sons and Daughters of the United States who voluntarily serve this great nation of ours are confused. Morale is being eroded throughout the ranks on this volatile issue. The common theme is a lack of trust. There have been numerous recantations of information that was originally put forth in regards to this vaccine. We are told time after time that the vaccine is entirely safe, yet there is a disparity between what we are told and what we are seeing.

My daily responsibilities are to help keep the men and women of Dover's AirLift Squadrons healthy and fit to fly.

Why are we seeing these unexplained illnesses?

Why was the vaccine originally marketed as entirely safe and used routinely by veterinarians for over 28 years?

Why are we told now that the long-term health effects of the vaccine are not known?

Why has there been a fluctuation in reaction rates?

Why is the FDA changing its package insert to reflect new data?

Why do we see a similarity between some of these illnesses and what was seen after the Gulf War?

Why were some vaccines used in the Gulf and not recorded in many individuals' shot records?

Why is morale low and retention rates in jepordy?

This along with the unanswered questions regarding Gulf War Illness only adds to the climate of confusion and mistrust. I fully understand the need for force protection and will dutifully obey the orders of the officers and civilians appointed over me, yet I feel bound by the core values to express my perspective to the sub committee. I would like to thank the committee for this opportunity to testify.

Mr. SHAYS. Thank you. Lieutenant Rovet.

Sergeant Soska.

Sgt. SOSKA. Congressman Shays, members of the committee, thank you for inviting me to testify today.

This last year has been difficult for my family and me because of the adverse effects I experienced after receiving the DOD-mandated anthrax vaccinations. I receive the injections as ordered on three occasions. The vaccine that I received came from lot FAV 020.

These ordered injections were administered during my deployment to Kuwait in support of Operation Southern Watch in 1998. Upon returning from Kuwait on June 10, 1998, I developed problems with my right arm, and a sore spot in my right wrist led to severe muscle spasm in my upper arm. These symptoms advanced to burning sensation in my fingertips, radiated to my left arm, and throughout the remainder of my body.

The pain in my ankle and joints at times is excruciating. On many nights, I am unable to sleep through the night because of the pain. I have trouble keeping food in my system. I have problems such as joint-muscle pain, swelling on my hands and feet, dizziness, memory loss, sleep disorders, one blackout, night sweats, chest pains, and shortness of breath.

Environmental changes cause the symptoms to increase with severity.

My condition continues to worsen. Problems and ailments have developed throughout most of my body. As with most long-term illnesses, some days are better than others, but the pain is always there as a constant reminder of the hardship and headache suffered by my family and me.

Although I continue to try to stay active and in shape, I am afraid I could be fighting a losing battle. As mentioned in my letter to Congressman Shays on April 29, 1999, many other soldiers are having similar problems, flu-like symptoms, chronic pain, and so forth.

The DOD reports that there are a low number of adverse reactions while they report a high rate of success for the AVIP. I have included in my reports that I sent to the Vaccine Adverse Events Reporting System [VAERS], as an attachment to my written statement. I hope those reports plus my testimony will cast doubt on the DOD claim that the AVIP is a successful program.

Soldiers who are getting sick are reluctant to report their symptoms out of fear of reprisal. The uncooperative spirit of military doctors makes bringing these symptoms to light seem like a lost cause to soldiers. The feeling is that there is a reluctance and even denial on behalf of the medical staff to inform their superiors so that proper treatment can commence.

Many soldiers have approached me with concerns for my condition. Our conversations, more often more of them realize they have many of the same symptoms. These symptoms are becoming prevalent in soldiers who did not even deploy to Kuwait but underwent AVIP.

I addressed my concerns over the AVIP during the Persian Gulf outreach meeting conducted by Mr. Rostker's staff at my duty location. I was present for three meetings. All I heard them say was,

we need you to come forward; we want to know what is happening to you.

However, in my opinion, the only thing that was really accomplished was a reiteration that the vaccine is safe. I was not the only person present that felt the meetings were an ineffective mode of covering up the truth about the anthrax vaccinations.

Soldiers are not being informed of the adverse effects as stated on the product inserts, nor were they being told about the various forms. I am charged with accomplishing the mission of looking out for the health and welfare of my soldiers. How can I accomplish my mission when the people who treat my soldiers are turning a deaf ear to their reports?

I have been told to come forward and let you know what is happening. I am here before you now, and like many, I am telling what I know but I feel my testimony is falling on deaf ears within the DOD.

My case is also unique. Since the onset of my symptoms, I have been persistent to investigate both my physical ailments and the program itself. I have written several Members of Congress. I have had the backing of my chain of command and the help of some outstanding doctors. I am one of the lucky ones. I am now being sent to the clinics to find out what is wrong with me.

But my question is, what will become of soldiers who have not aggressively sought diagnosis and treatment but accepted their plight? What will be done to ensure that they are getting the same care?

Being an NCO is a rewarding career. I have invested 17 years in the proud service of my country. I have no regrets. I did what was asked of me, and now I am sick. I must stand up for what I feel is moral and ethically right. I am here to testify that this program is wrong.

Procedures are not being followed as spelled out in the AVIP documents. Soldiers are getting sick at an alarming rate. Soldiers should not be made to feel afraid to come forward with their medical complaints; soldiers need to come forward and inform responsible and caring physicians of their symptoms.

When they do come forward, they should not be told the symptoms are all in their heads or that there is nothing to worry about.

Soldiers deserve better.

This concludes my opening statement, Mr. Chairman.

[The prepared statement of Sgt. Soska follows:]

Statement of SSG Robert H. Soska Jr,

Before the Subcommittee on National Security, Veterans Affairs and

International Relations

Christopher Shays, Chairman

Committee on Government Reform

U. S. House of Representatives

21 July 1999

Testimony of SSG Robert H. Soska Jr.

Committee on Government Reform

Subcommittee on National Security, Veteran's Affairs and International Relations

Hearing on Anthrax Vaccine Safety, July 21, 1999

Congressman Shays, members of the Committee, thank you for inviting me to testify today. I am here to give my personal testimony in regards to the adverse effects that I experienced after receiving mandated anthrax vaccinations. The Department of Defense (DOD) through the Anthrax Vaccination Inoculation Program (AVIP) mandated these injections. I received the injections, as ordered, on three occasions. The vaccine that I received came from lot # FAV020. These ordered injections were delivered during my deployment to Kuwait during Operation Southern Watch. As mentioned in my letter to Congressman Shays on 29 April 1999, many soldiers are having problems. The DOD reports that there are a low number of adverse reactions while reporting a high rate of success over the AVIP. I have included the reports that I sent to the Vaccine Adverse Events Reporting System (VAERS) as an attachment to this document. I hope that my testimony will cast doubt on these claims.

Soldiers are getting sick but are reluctant to report their symptoms out of fear of reprisal. The uncooperative spirit of the military doctors make bringing these symptoms to light seem like a lost cause to the soldiers. The feeling is that there is a reluctance and even denial on behalf of the medical staff to inform their superiors so that proper treatment can commence. Many soldiers have approached me with concern for my condition. In our conversations, more and more of them realize that they too have many of the same symptoms. These symptoms are becoming prevalent in soldiers that did not deploy to Kuwait but underwent AVIP.

This last year has been difficult for my family and me. Upon returning from Kuwait, I developed problems with my right arm. A sore spot on my right wrist led to severe muscle spasms in my upper arm. These symptoms advanced to a burning sensation in my fingertips, radiated to my left arm, and throughout the remainder of my body. The pain in my ankles and joints, at times, is excruciating. On many nights, I am unable to sleep through the night due to the pain. I have trouble keeping food in my

system. I have problems such as joint and muscle pain, swelling of my hands and feet, dizziness, memory loss, sleep disorders, one black out, night sweats, chest pains and shortness of breath. Environmental changes cause the symptoms to increase with severity. My condition continues to worsen. Problems and ailments have developed throughout most of my body. As with most long-term conditions, some days are better than other days but the pain is always there as a constant reminder of the hardship and heartache suffered by my family and me because of AVIP. I continue to try to stay active and in shape. However, it is not easy.

During Operation Southern Watch of last year, a small group of soldiers from the 123rd Signal Battalion was deployed to support the 3rd Infantry Division communications links. We deployed to Kuwait in February 1998 and established operations. We heard rumors that we were all going to receive the Anthrax vaccine during March. On 23 March 1998, my section was given our first injection. We were not informed of any potential adverse side effects other than a burning sensation and tenderness at the injection site. We were not informed of the VAERS. All were given the hand out ***What Every Person needs to know About the Anthrax Vaccine***. All had to complete a health form questionnaire and turn it in a day or so prior to receiving the vaccination. The only other information we received stated that if we refused to take the shot we would be given UCMJ action. In the spirit of loyal service of our country, we complied and put our faith in the system. Two more shots were given on 6 April and 26 April 1998.

Please understand that many in the group were uncomfortable with accepting the vaccination. In the days that followed the injections, we all felt weak and tired. Many of us contracted cold symptoms. We had no idea what was happening to us. Many felt it was related to the change of environment, nerves, and being away from home. We were exposed to many factors while deployed to Kuwait. The food was often less than desirable. Many fell ill to stomach problems. Several times during our stay, we received medicine as if it were candy. The medics were having a time of it to say the least. Either you had acute diarrhea or you were so constipated that you would regret going to the latrine. Sometime during April or May, I broke out with a rash on the bottom of my feet and began to have lower back pain.

I soon realized that I was not the only one experiencing these problems. Others that deployed with the 3rd ID began to experience the same problems after our return home. We began to compare symptoms and cross-talked. Unlike the others, I had everything documented in my medical records since the onset of my symptoms. I advised them to do the same and register with the Persian Gulf Registry. I also advised them to go on sick call and get it documented in their medical records. Many listened to my advice and others did not. I also informed them of the VAERS forms. Again, some followed my advice and many did not. I distinctly remember several of my soldiers having problems with unexplained rashes and various other problems over this last year. One of my soldiers, who did not deploy with us, was also experiencing similar reactions. I informed my chain of command of my situation and graciously received a postponement of the follow-up shots. This information was echoed up the chain of command. I even informed the doctor treating me at the time that I felt the vaccine was part of the cause of my illness. He indicated that it would be difficult to say. I returned to sick call when the fatigue got so bad that I could hardly stay awake at work. It was discovered that I was losing Vitamin B12 from my system. The doctor ordered B12 injections. My doctor felt I was suffering from Fibromyalgia. To date, My system is still loosing B12.

On 27 January 1999, I was ordered to report to Jordan Jim to update deployment packet and update my immunizations. During this time, I was suffering seizure-like spells and headaches that made me feel weak and numb. Upon reaching the immunization line, I informed the medic that I was on B12 replacement shots and that I felt it would not be a good time to get my next anthrax shot. The Specialist took me to the NCOIC and informed her of my situation. She agreed and said that I needed to see if I could get on the exemption list. I was so relieved to hear her say that I did not have to get the injection. The only shot I received was the Meningoccal vaccination.

28 January 1999 I reported back on sick call as I was still having problems with dizzy spells and headaches. The other symptoms were still present.

29 January I felt a little dizziness coming on shortly before leaving my residence for work. During formation at 0915, I became very lightheaded and my hands began to swell. Another Sergeant made

reference to the massive swelling in my hands. I told my Platoon Sergeant, SFC Skidmore, that I didn't feel very well and that I was going on sick call. This was unlike anything I had experienced up to this point. I felt as if all my joints and muscles were freezing up and I became very dizzy and numb. My chest began to swell and it became difficult to breathe. I managed to walk by myself to the Troop Medical Clinic where a female medic helped me get to the treatment room. I mentioned to the examining doctor that I just had a MGC shot on the 27th. At that point, I was administered oxygen and my shirt was removed. The remaining details are fuzzy at best. I remember the doctor telling the medic to get another blood pressure reading. I did not remember the first reading being taken. He told me that I was out of it for a while. I was sent home on Quarters. Shortly after this event, my doctor set up an appointment with neurology at Fort Gordon Medical Center. These same symptoms continued through April but at a decreasing rate of severity.

23 February 1999, I was ordered by my 1SG to report to the Troop Medical Clinic (TMC) to get my next anthrax vaccination. I was still experiencing numbness, headaches, and other symptoms. Upon entering the TMC, I asked my doctor to postpone the treatment. My request to see him was accepted. I again told him about my apprehension in receiving my fourth shot. I shared my belief that it was the injections that was making me sick. Even the product insert states that it should only be administered to healthy individuals. He said something like; "I can't understand why so many people are so worried about this shot. It has nothing to do with your situation!" He obliged though and deferred the shot until I was seen by Neurology clinic at Ft Gordon.

The most disturbing part about my entire situation is that no one seems to know what is causing the symptoms. I have been to many clinics and talked with several people in the medical profession. Still, not one of these has been able to pin down the cause or tell me what I can do to get better. All they can offer is treatment for the symptoms. When I mention what happened to me after taking the anthrax vaccinations or when I show them the letters I have sent VAERS, they take the defensive. I hate to say it, but I am worried about my future. Where will I be two years from now? What effect is this going to have on my wife and three children? Finally, what will I do if I can no longer work? Will I fall into the same pit that many of the Gulf War vets have?

I mentioned earlier that other soldiers were experiencing similar problems. Many deployed with us to Kuwait and others did not. I have done all I can to get them to seek help; but many are afraid of being drummed out of the service. The general feeling in the ranks is that nothing will come of it so what's the use. This is too big for our complaints to make a difference. They are being told this all in their heads or they simply have the Flu… I disagree with this line of thought. Every Soldier has a right to voice his or her complaints.

Over the last year, I have seen my fellow soldiers become ill with strange rashes, chronic fatigue, and sleep disorders. In a discussion with my commander I mentioned what I had seen happening to other soldiers in my command shortly after being vaccinated. I believed that it was my responsibility to look out for their health and welfare. I thanked him for taking the time to listen to me and letting me share my insights and personal experiences with him. It was during this conversation, that I informed him I was thinking about testifying during the next hearing. He said, "Why are you thinking about it, why aren't you doing it!" I was elated by his encouraging tone of voice and said, "Sir, you're right, I am going! Please inform the chain of command of my intentions."

I have a listing of all the troops that deployed with me to Kuwait. I believe that an inquiry into the DOD's outstanding Tracking program would reveal that many of these soldiers are experiencing the same effects that I experience. I believe that a more in depth inquiry would reveal these symptoms to be present in a large percentage of all the military men and women that have received this vaccination.

I addressed my concerns over the AVIP during the Persian Gulf Outreach meetings conducted by Mr. Rostker's Staff. I was present for three meetings. All I heard them say was that, "We need you to come forward, we want to know what is happening to you!" The only thing, in my opinion, that was accomplished was the reiteration of the safety of the vaccine. I was not the only person present that felt the meetings were an ineffective mode of covering up the truth about the Anthrax Vaccination.

Soldiers are not being informed of the adverse affects as stated on the product insert, nor were they being told about the VAERS forms. I am charged with accomplishing the mission and looking out for the health and welfare of my soldiers. How can I accomplish my mission when the people who treat my soldiers are turning a deaf ear to their reports? I have been told to come forward to let you know what is happening. I stand before you now and like many, I am telling you but I feel like my testimony is falling on deaf ears.

My division Surgeon was also in attendance. He stood up and said he wanted to know who these soldiers were. Shortly after the meeting, I presented him my medical record and VAERS information. As a result of this meeting, I am on my way to Walter Reed's Immunology clinic. Again, my fate is in the hands of others that have the power to decide whether I receive further Anthrax vaccinations. I am terrified of having more vaccinations.

I have had several conversations with LTC Gamble and our new Division Surgeon, LTC Garigan. During our conversations, they both found it hard to believe that soldiers are afraid to come forward. LTC Garigan told me he was one of the 100 Physicians that attended the Ft. Detrich meeting. I told him that I was aware of that meeting. I do not remember everything that was said but I told Mr. Halloran over the phone that I received the impression that they are trying to make changes and that they realize soldiers are having problems. I am grateful for his concern and his help in stabilizing me to complete both the Persian Gulf Physical and the work up at Walter Reed's Immunology Clinic.

My case is unique. I have been persistent since the onset. I have written several members of congress. I have had the backing of my Chain of Command, and help of some outstanding doctors. I am one of the fortunate ones, I am being sent to the clinics in an attempt to find out what is wrong with me. What will become of the soldiers that have not displayed this diligence? What will be done to ensure they are getting the same care?

I can not help but feel despair at what is happening here. What ever happened to taking care of soldiers in service to their country? Why are the guidelines being ignored for systemic reactions as spelled out in the product insert? How can the DOD say that it would be unethical to not give us these vaccinations when the Surgeon General of the Army stated in Senate report 103-97 that it may be the cause of what is making many of us sick? How do you justify a vaccine that has not been tested for long-term side effects? Soldiers should be told what to expect and informed of the risks associated with anthrax shots prior to be injected.

I have seen Certificates of Immunization that did not have the Lot numbers recorded. I checked my soldier's forms and instructed them to go back and get the lot numbers. I assure you, there are many more just like this that have just the vaccine's name and dose amount recorded. Others have told me that the records are kept by their Training Sergeants and are not recorded in their medical records. How can a soldier report a reaction to VAERS when they do not know what lot numbers they have been given?

The VAERS program in my opinion is working. You can see for yourself that they have been concerned for me since my first report. My only concern is that many of the forms being filed are not being added to the VAERS database. I discovered this when I called to check the status of one of my soldier's VAERS form. His form was missing from the database and had not been entered. The person informed me many times when the information is not entered or Block 8 is left blank that the forms are thrown out. A key element that is missing is the lot numbers.

I have spent the better part of a year trying to find out what is physically wrong with me. During that time, I have educated myself. I have read reports stating that The FDA cited the MBPI for unsafe manufacturing practices. I also learned that lot number FAV020, which I was inoculated with, is one of the most questionable lots. When I read the Letter of Understanding between the FDA and DOD I could not help but get the feeling that both share the responsibility equally. The GAO report is yet another document that makes a soldier wonder. When will the DOD print the truth and retract statements or pamphlets like the tri-fold they gave us in Kuwait? If it were not for the vocal minority, we would never have found out that veterinarians have not been getting the shots since 1970. Over the last three months more and more evidence has been uncovered to show that we are not being told the truth. When will all

the misinformation from DOD end and the truth be told?

Being a NCO is a rewarding career. I have invested 17 years into proud service for my country. I have no regrets. I did what was asked of me and now I am sick. I must stand up for what I feel is morally and ethically right. I stand here before you and testify that this is wrong. Procedures are not being followed as spelled out in the AVIP documents. Soldiers are getting sick at an alarming rate. Soldiers should not be made to feel afraid to come forward with their medical complaints. Soldiers need to come forward and inform responsible physicians of their symptoms. When this happens they should not be told that it is all in their heads or that it is nothing to worry about. Soldiers deserve better.

I have listened to the stories of my fellow sergeants, soldiers and others that are experiencing problems. I am not a doctor, neither am I an idiot. It is evident that this problem is bigger than the military realizes or reports.

I would like to commend people like Dr Meryl Nass, LTC Garigan, our support channel, the people at the Persian Gulf Illness clinic at Ft Stewart, the VAERS Staff and surgeons who have been working with me. They have kept me going over this past year. Dr. Nass was there when no one else would listen to me. She was the one who encouraged me to ask the tough questions and to keep fighting. I also want to thank my Congressman, Paul Coverdale for his assistance. I especially want to thank my chain of command for their guidance and genuine concern for my personal health.

In conclusion, I want to thank this committee for your concern regarding our reactions to this vaccine. I ask that you ensure that we soldiers who are sick receive the appropriate care and medical attention we desperately need. We can not do this on our own. I also ask that you prevent this from happening to other soldiers before it disables a large portion of our military as a whole and adversely affects our national defense.

Respectfully Submitted,

SSG Robert H. Soska Jr.

United States Army

Mr. SHAYS. Thank you, Sergeant Soska.

Captain Richter.

Capt. RICHTER. Good morning, Congressman Shays, committee members. Thank you for the invitation to appear before you. Yes, my name is Captain Richter, and at this point I am really happy I suffered through Public Speaking 101 in college. [Laughter.]

I, too, am a C–5 pilot in the U.S. Air Force Reserve at Dover Air Force Base in Delaware. Like my father and my grandfather before me, who are both career Naval officers, the military has been an integral part of my life. For over 12 years now, I have served as an aviator in both the Navy and the Air Force.

I am not a malcontent nor do I have any personal vendetta against the military. On the contrary, I have served proudly and faithfully through Desert Storm in the Navy and through Operation Provide Comfort and Northern Watch in the Air Force.

I am not here representing the Air Force or the Department of Defense. These are my view and opinions only. I am simply here to tell you my story.

In June 1998, I left the active-duty Air Force as a special operations pilot at Hurlburt Field, Florida. I was accepted into the Air Force Reserve and went to C–5 Galaxy pilot training, which I completed in January 1999. Upon the return of my unit in Dover, I was told that all personnel needed to start the anthrax vaccine series of shots if they had not already done so.

I had heard a few of my peers discussing the vaccinations and possible unpleasant side effects in various cases and how they would quit before being forced to take it. I dismissed the talk as rumors and innuendo, thinking that the military wouldn't vaccinate the troops with something unsafe or unproved.

I took my marching orders, saluted smartly, and went to the clinic for the first of my shots on February 3, 1999. I was injected with lot number FAV 030. I had no noticeable negative reaction. No one at the squadron asked me, nor did anyone at the clinic question me if I had experienced any negative reactions before I went in for my next injection.

On February 19, 1999, I submitted to the next shot in the series, which were to be 2 weeks apart. I was again injected with lot number FAV 030. Approximately 5 days later, the problems began. My right shoulder joint started to ache, much like when I had played catch as a kid without properly warming up.

A few days later I noticed my left shoulder joint aching. I thought it was odd. About a week later, I experienced pain in the center of my spine, to the point that I had some difficulty getting out of bed in the morning. These aches and pains lasted for several weeks each before dissipating.

Again, there was no followup from any medical personnel to discuss any possible negative reactions to the vaccine.

In April, my ankles and feet began to hurt as well as my left thumb and index finger joints. I noticed swelling in my hand. I was not starting to register genuine concern. I could not get out of the bed without limping with pain for the first few hours until my body loosened up.

Today the pain has stabilized mostly in my feet and left hand, with an occasional flare-up somewhere new in my body. Last week

it was my hip joints; next week it may be something else. I awaken and ease into my day with a couple of over-the-counter Motrin. I cannot walk without a limp and severe discomfort for the first hour.

Furthermore, if I am stationary for more than an hour during the day, my joints and muscles stiffen, making movement extremely unpleasant.

I have lost flexion in my left thumb, and it is still swollen. I am a 36-year-old man with no previous history of arthritic symptoms, and I was perfectly healthy before my first anthrax shot.

In May, I learned that Colonel Felix Greider, 436th Airlift Wing Commander, at Dover Air Force Base had boldly decided to suspend all further vaccinations until information was available on the vaccine and the concerns of his people were addressed. I quietly applauded this gallant decision, as I decided that taking a third shot in the series was not in my best interest.

Shortly thereafter, the Air Force surgeon general, Lieutenant General Charles Roadman, came to Dover to discuss the anthrax vaccination program and hopefully assuage the doubts of base personnel. I was not in attendance, but learned through a few people who were that Lieutenant General Roadman assured everyone the vaccine was completely safe and that only a minute percentage of those military personnel inoculated had a negative reaction.

Meanwhile, I was encountering more of my squadron mates who were vaccinated that said they too had experienced various reactions, including tinnitus, dizziness, muscle and joint pain, and, in one case, gray-outs.

However, most were attempting to keep it low-profile and did not readily discuss these matters for fear of reprisal.

In June, as I became more and more concerned that my condition was not getting better, I took the initiative to discern what is going on in my body. I learned from what is now a full-scale anthrax information network among my peers that 1st Lieutenant Rovet and Tech Sergeant Domm were taking information on anthrax vaccine reactions for entry into the VAERS data base.

After meeting with Tech Sergeant Domm and speaking to 1st Lieutenant Rovet over the phone, they convinced me to come forward and go public, so to speak, about my condition and to encourage others who were vaccinated and are having problems to do so as well. They also gave me the number of the Allergy-Immunology Clinic at Walter Reed Army Medical Center.

On June 23, 1999, I called the immunology clinic at Walter Reed and was seen that same day. After discussing my symptoms and stating my concerns about continuing the anthrax vaccination program, the doctor ordered a series of blood tests.

In paraphrasing our conversation, he told me he could take blood tests to determine that I do not have rheumatoid arthritis, but there are no tests that could positively link my condition to the injection of the anthrax vaccine. The doctor then gave me a temporary waiver from taking the next anthrax injection until my blood-test results were returned for review.

He later informed that the results of the blood test revealed that I was not positive for rheumatoid arthritis factor.

Therefore, he stated, that he would in all likelihood ultimately have to recommend that I continue the anthrax vaccination shot series.

I told him that put me in a very tenuous situation, and one that left me with only one clear option. The doctor went on to say, and I am again paraphrasing here, that the threat of being exposed to anthrax while on a deployment outweighed the possible negative reactions that some military personnel might have to the vaccination and that it was not a matter of if but when some of our troops would come in contact with it.

I am unsure if this was his opinion or Department of Defense policy. Apparently there is an unusually high level of acceptable risk with this vaccine.

The squadron policy and I assume the 512 Airlift Wing policy was clearly and unequivocally stated in June. We were told the next time a drilling reservist comes into drill, he or she will commence the anthrax vaccination series or continue with the next injection if the series was already begun.

This policy was re-emphasized on or about July 7, 1999, when I got a phone call at my home from my unit saying the next time any reservist planned to drill he or she had to take an anthrax shot or turn in an Air Force Form 1288, which is a resignation form, or be subject to Uniform Code of Military Justice Article 15 procedures.

Currently, approximately 60 percent of my squadron's pilots are quitting the Reserve military because they have been forced to make a decision to gamble with their health. I can only assume that the people in the other specialties required to execute the mission of an airlift airplane such as the C–5 are leaving as well.

Word travels fast. Morale is at an all-time low. People are trigger-shy about coming forward with their symptoms. There is an air of fear and distrust prevalent throughout.

By coming here today, I have most assuredly fallen on my sword. I recently made the rank of major, but I never expect to be able to wear it because I will resign before I take another anthrax injection. This is sad because I like my job. I love my country. The military has always been a part of my life, and I had planned on continuing to serve in it.

I am just a captain and a very small cog in the huge wheel of the military, but I am the guy in the trenches of the DOD's implementation of the anthrax vaccination program.

I am not a medical professional, but I am medically qualified to discuss one thing, and that is the status of my own health.

I was healthy before, now I am not. I know what is good for me and what is not. And right now, taking another shot is not part of the John Richter health-care program.

Those in command seem to have shrugged their shoulders at the numbers of people leaving military with the attitude that an order was given and it should be carried out. We are growing tired of the denials that everything is OK when, in fact, it isn't.

Over 12 years ago, I raised my right hand and solemnly swore to support and defend the Constitution against all enemies foreign and domestic and to obey the orders of the officers appointed over me. I took that oath freely and willfully. I knew that I could and

would give my life for my country, and on several occasions during the course of my military flying career, I almost made that sacrifice, as have many others.

But at no time did I ever agree to be slowly poisoned, however well-intentioned, under the guise of being combat ready so that every day is one filled with pain. That wasn't part of the contract as I know it.

I have defended my country and I have obeyed the orders of the officers over me, but taking another anthrax shot is not an order I can carry out.

Thank you.

[The prepared statement of Capt. Richter follows:]

CAPT Richter July 21 Test

Good morning. My name is Capt Jon Richter and I'm a C-5 pilot in the U.S. Air Force Reserve at Dover AFB in DE. Like my father and grandfather before me, who were both career naval officers, the military has been an integral part of my life. For over 12 years now I have served as an aviator in both the Navy and Air Force. I am not a malcontent nor do I have a personal vendetta against the military. On the contrary. I have served proudly and faithfully through Desert Storm while in the Navy and Operation Northern Watch in the Air Force. I am not here representing the Air Force or the Department of Defense. These are my views and opinions only. I am simply here to tell you my story

In June of 1998 I left the active duty Air Force as a special operations pilot at Hurlburt Field, FL. I was accepted into the Air Force Reserve and went to C-5 Galaxy pilot training which I completed in January of 1999. Upon return to my unit in Dover, I was told that all personnel needed to start the anthrax vaccine series of shots if they had not already done so. I'd heard a few of my peers discussing the vaccination and possible unpleasant side effects in various cases and how they would quit before being forced to take it. I dismissed the talk as rumor and innuendo thinking that the military wouldn't vaccinate the troops with something unsafe or unproved. I took my marching orders, saluted smartly and went to the clinic for the first of my shots on 3 Feb 99. I was injected with lot # FAV 030. I had no noticeable negative reaction. No one at the squadron asked me nor did anyone at the clinic question me if I'd experienced any negative reactions before I went for the next injection. On 19 Feb 99 I submitted to the next shot in the series which were to be two weeks apart. I was again injected with lot # FAV 030. Approximately five days later, the problems began. My right shoulder joint started to ache much like when I'd played catch as a kid without properly warming up. A few days later, I noticed my left shoulder joint aching. I thought it was odd. About a week later, I experienced pain in the center of my spine to the point that I had some difficulty getting out of bed in the morning. These aches and pains lasted for several weeks each before dissipating. Again there was no follow-up from any medical personnel to discuss any possible negative reactions to the anthrax vaccine.

In April, my ankles and feet began to hurt as well as my left thumb and index finger joints. I noticed swelling in my hand. I was now starting to register genuine concern. I could not get out of bed without limping with pain for the first few hours until my body loosened up. Today, the pain has stabilized mostly in my feet and left hand with an occasional flare up somewhere new in my body. Last week it was my hip joints and next week maybe something else. I awaken and ease into my day with a couple of over the counter Motrin. I cannot walk without a limp and severe discomfort for the first hour. Furthermore, if I am stationary for more than an hour during the day, my joints and muscles stiffen making movement extremely unpleasant. I have lost flexion in my left thumb and it is still swollen. I am a 36 year old man with no previous history of arthritic symptoms and I was perfectly healthy before my first anthrax shot.

In May I learned that Col. Felix Greider, 436th Airlift Wing Commander at Dover AFB, had boldly decided to suspend all further vaccinations until more information was available on the vaccine and the concerns of his people could be addressed. I quietly applauded his gallant decision as I'd decided that taking the third shot in the series was not in my best interest. Shortly thereafter, the Air Force Surgeon General, Lt. Gen. Charles Roadman, came to Dover AFB to discuss the anthrax vaccination program and hopefully assuage the doubts of base personnel. I was not in attendance but learned through a few people who were there that Lt. Gen. Roadman assured everyone the vaccine was completely safe and that only a minute percentage of those military personnel inoculated had had a negative reaction. Meanwhile, I was encountering more of my squadron mates who were vaccinated that said they too had experienced various reactions including tinnitus, dizziness, muscle and joint pain and in one case black-outs. However, most were attempting to keep a low profile and did not readily discuss these matters for fear of reprisal.

In June, as I became more and more concerned that my condition was not getting better, I took the initiative to discern what is going on in my body. I learned from what is now a full-scale anthrax vaccine information network among my peers that 1Lt Rovet and TSgt Domm were taking information on anthrax vaccine reactions for entry into the VAERS database. After meeting with TSgt Domm and speaking to 1Lt Rovet over the phone, they convinced me to come forward and "go public," so to speak, about my condition and to encourage others who were vaccinated and are having problems to do so as well. They also gave me the number of the Allergy-Immunology Clinic at Walter Reed Army Medical Center. On 23 Jun 99 I called the immunology clinic at Walter Reed and was seen that same day. After discussing my symptoms and stating my concerns about continuing the anthrax vaccination program the doctor ordered a series of blood tests. In paraphrasing our conversation, he told me he could take blood tests to determine that I do not have rheumatoid arthritis but there were no tests that could positively link my condition to the injection of the anthrax vaccine. The doctor then gave me a temporary waiver from taking the next anthrax injection until my blood test results were returned for review. He later informed me that the results of the blood tests revealed that I was not positive for rheumatoid arthritis factor. Therefore, he stated that he would in all likelihood ultimately have to recommend that I continue the anthrax vaccination shot series. I told him that put me in a very tenuous situation and one that left me with only one, clear option. The doctor went on to say, and I am again paraphrasing, that the threat of being exposed to anthrax while on a deployment outweighed the possible negative reactions that some military personnel might have to the vaccination and that it was not a matter of if but when some of our troops would come in contact with it. I am unsure if this was his opinion or Department of Defense policy. Apparently there is an unusually high level of acceptable risk with this vaccine.

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got a phone call at home from my unit saying that the next time any reservist planned to drill, he or she had to take an anthrax shot, or turn in an AF 1288 (resignation form) or be subject to Uniform Code Of Military Justice Article 15 procedures. Currently, approximately 60% of my squadron's pilots are quitting the reserve military because they've been forced to make a decision to gamble with their health. I can only assume that the people in the other specialties required to execute the mission of an airlift airplane such as the C-5 are leaving as well. Word travels fast. Morale is at an all-time low. People are trigger-shy about coming forward with their symptoms. There is an air of fear and distrust prevalent throughout.

By coming here today, I have most assuredly "fallen on my sword." I recently made the rank of major but I never expect to be able to wear it because I will resign before I take another anthrax injection. That is sad because I like my job. I love my country. The military has always been a part of my life and I'd planned on continuing to serve in it. I am just a captain and a very small cog in the huge wheel of the military. But, I am the guy in the trenches of the DOD's implementation of the anthrax vaccination program. I am not a medical professional. But I'm medically qualified to discuss one thing and that is the status of my own health. I was healthy before, now I am not. I know what's good for me and what is not. And right now, taking another shot is not part of the Jon Richter healthcare program. Those in command seem to have shrugged their shoulders at the numbers of people leaving military service with the attitude that an order was given and it should be carried out. We are growing tired of the denials that everything is okay when in fact it isn't. Over twelve years ago, I raised my right hand and solemnly swore to support and defend the constitution against all enemies foreign and domestic and to obey the orders of the officers appointed over me. I took that oath freely and willfully. I knew that I could and would give my life for my country. And on several occasions during the course of my military flying career I almost made that sacrifice as have many others. But at no time did I ever agree to be slowly poisoned, however well intentioned, under the guise of being "combat ready" so that every day is one filled with pain. That wasn't part of the contract as I know it. I have defended my country and I have obeyed the orders of the officers appointed over me. But taking another anthrax shot is not an order I can carry out. Thank you.

Jonathan E. Richter

CAPT USAFR

Mr. SHAYS. Thank you, Captain Richter. How many years have you served in the military, sir?

Capt. RICHTER. Almost 13.

Mr. SHAYS. Thank you.

Lieutenant Colonel Jensen. You will conclude.

Col. JENSEN. Yes, sir. Mr. Chairman, distinguished members of the subcommittee, I am Lieutenant Colonel John Jensen, wing chief of safety for the 120th Fighter Wing, Great Falls, MT, Montana Air National Guard.

I am here today in response to your invitation seeking my views and experience with regards to the AVIP program. The views expressed in my testimony are my personal views and not meant to be taken as those of the DOD, Air Force, Air National Guard, or my command.

As a military member since 1979, I was raised in a family of military service, with my grandfather serving in World War I and my father serving during the Korean conflict as a Marine fighter pilot. I joined the Marine Corps in 1979, following in my father's footsteps and am continuing to serve my country today in the Air National Guard.

In my opinion, one of the biggest challenges to the success of the AVIP program is understanding all of the issues and perceptions that exist out there, even those perceptions that do not follow the party line. I feel that if commanders in senior leadership do not understand the intricacies of the issues that have arisen out of the anthrax vaccine, they will be ill-equipped to meet the concerns raised by the field.

Accurate, consistent, non-conflicting information is the key. In my research to enhance my knowledge and understanding of these issues, I have come across two areas that concern me greatly. First, there appears to be a perception in the field that they are not being given accurate, consistent information on the vaccine, to include its safety and efficacy, and as a result, they are losing or, in some cases, have lost their trust in the DOD. Second, it is perception or lack of trust may be impacting our force readiness.

The following is provided in hopes that the committee can better understand and fully appreciate these two significant challenges that I feel we face today.

Before proceeding, I would like to offer my view of those who serve in the military today, as I believe this is a key element in meeting the challenges cited above. There is no doubt in my mind that those volunteers who serve their country today are the most educated and best trained in our country's history. They are trained and qualified to work, maintain, and employ some of the world's most sophisticated equipment in the most demanding of environments.

They are taught such things as risk-management, ethics, law of armed conflict, and the importance of accountability. Since my written testimony covers in great deal those items that bring to light the concerns and challenges cited above, I will address only a few in this testimony.

Acknowledged: The threat of a biological attack of anthrax has existed since 1990. There is a vaccine available that either by itself or in conjunction with chemical warfare gear and/or post antibiotic

treatment should significantly increase one's survival rate if subjected to an anthrax attack.

Concern: Anecdotal evidence indicates the reaction rate of AVA exceeds the product insert and what the field is being told. Anecdotal evidence shows the AVA is at least temporally associated with systemic reactions, hospitalization, cardiac events, and symptoms similar to those suffered in Gulf War Illness Syndrome.

The anthrax vaccine will not be completely safe based upon the above concerns and/or due to the improper manufacturing procedures identified by the FDA and testified to by the GAO.

Examples that I feel are fueling the perception that the field is not being given consistent, up-front, accurate information: The VAERS reporting system used to substantiate the adverse reaction rates cited by DOD is perceived as not being impartial. The FDA requests and encourages VAERS reports on all reactions, even those that only temporally associated with vaccines.

The AVIP program filters the VAERS system. It requires the reporting of events that only result in hospitalization or 24 hours loss of duty. AVIP requires recording severe local reactions and systemic reactions in the medical records but directs that these will not be reported unless contamination of the lot is suspected.

VAERS forms do not go directly to the FDA. They are reviewed at least once more prior to reaching the FDA. This filtering has one tremendous downside, it does not allow for the identification of less severe reactions which may indicate a problem that may be occurring in large numbers across the population.

The public recently learned that the Secretary of Army granted indemnification to the anthrax vaccine manufacturer in 1998. The DOD states this is a normal procedure to reduce insurance costs to the company.

A Pentagon spokesman is reported in the paper as saying that the last time an indemnification was given for a vaccine was in 1976 for the swine flu.

Next, a letter of indemnification appears on the web, signed in 1991 by the Secretary of the Army, granting indemnification to PRI for the production of anthrax vaccine to be shipped to MDPH, where MDPH was to bottle, label, and test.

This indemnification states, quote:

> The obligation assumed by PRI under this contract involves unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the anthrax vaccine. These concerns stem from: a) the limited use of the vaccine to date, i.e., tests prior to the approval of a vaccine by the Food and Drug Administration are too small a scale to permit accurate assessments of the types and severity of adverse reactions. Only widespread use can provide this assessment. And b) insufficient experience in mass immunization programs to truly evaluate the efficacy of the vaccine. Moreover, there is no way to predict whether the pathogen against which the vaccine may be used will be sufficiently similar to the pathogen used in tests to ensure vaccine efficacy.

Mr. SHAYS. Is that still a quote?

Col. JENSEN. Close quote. Yes, sir.

Mr. SHAYS. All of that is from the indemnification letter?

Col. JENSEN. Yes, sir. I have a copy, if the committee would like.

Mr. SHAYS. We do too. Thank you.

Col. JENSEN. How does a health-care worker or commander respond to this when presented it by a troop?

Unfortunately, accurate vaccine records identifying the approximately 150,000 individual vaccinated during the Gulf war with AVA do not exist. I have read that this vaccine's systemic reactions are no worse than those of hepatitis A or typhoid or other vaccines.

This may be true. But shouldn't the issue be, are the actual reaction rates in line with the expected rates and types for which the FDA licensed it, not how they compare to other vaccines?

Some people say the benefit outweighs the risk. My only question of this, and hopefully the committee can provide an answer, is, what exactly is the risk.

My first impression of the vaccine's side effects were those stated in the product insert and quoted by numerous officials. Are those the risks? Or is the risk ending up like those individuals that have previously testified before this committee and those testifying here today, assuming the anthrax vaccine is the cause of their ailments.

Finally, will this yet undefined risk increase or decrease over time as the number of those vaccinated increase, thereby increasing our data base.

Greatest fears: AVA, a potentially valuable force protection tool may not be available: The program may be killed by Congress due to poor communication, i.e., the field perceives they are not being provided the whole story.

Force readiness is being compromised, the trust issue. The following are some of the effects that the AVA program appears to be having on our retention. I would offer that those leaving over this have made a benefit-outweighs-the-risk assessment, and their version is, the risk does outweigh the benefits.

Dover Air Force Base, supposedly 30 to 40 percent of the air crew—pilots, flight engineers, loadmasters—have or intend to resign vice take the vaccine.

Connecticut Air National Guard, eight pilots forced to resign after they refused to take AVA. Note, some of these pilots were part of a information-gathering team directed by the commander. They refused to take the vaccine after the issues raised in their research could not be answered.

Wisconsin Air National Guard, the story ran in the Madison Newspapers, Inc., June 19, 1999: At least six pilots are expected to refuse the vaccine. Note, one was in line to be the next squadron commander.

Travis Air Force Base, 17 tanker air crew resigned from the 79th. Thirty-one pilots out of the 301st have submitted resignations. The number is expected to climb to over 60 percent by the end of fiscal year 1999. That is 429 years of flying experience gone.

I am told an IG complaint is pending due to an individual's 1288 reflecting job conflict as the reason for leaving, vice AVA.

From the above, it appears that before units are even moving to enter the theater where anthrax may or may not be used, their combat readiness is being compromised, in some cases, by as much as 50 percent.

Important note: People are not leaving because they have read some article on the dark side of the web. They are leaving because they have seen people with whom they have served for years, and in some cases combat, take the vaccine, become ill, and no reason given to as why other than we know it is not the vaccine.

To the end, those with whom I have talked, state that they are leaving because of the vaccine and that they have lost their trust in their leaders.

In closing, I would ask not only the committee but those commanders who read and hear this testimony to take an honest look at the AVIP program, the issues raised above, and those being raised in the field.

My purpose in testifying here today is not to kill the AVIP program. I welcome a vaccine that would protect not only myself but those whom I am entrusted to lead into battle, provided it is truly safe and effective.

It troubles me deeply to watch outstanding service members leave in the fashion that they are.

Finally, it would be irresponsible of me as both an American citizen and military officer had I chosen the easy path and declined your offer to testify here today.

Mr. Chairman, integrity begets loyalty, loyalty does not beget integrity.

Thank you.

[The prepared statement of Col. Jensen follows:]

Prepared Statement of Lieutenant Colonel John C. Jensen

Before the Subcommittee on National Security, Veterans Affairs

and International Relations, Committee on Government Reform

of the U.S. House of Representatives

July 21, 1999

Mr. Chairman, distinguished members of the Subcommittee, I am Lt. Col. John Jensen, Wing Chief of Safety for the 120th Fighter Wing, Montana Air National Guard, Great Falls, MT. I am here today in response to your invitation seeking my views and experiences with regards to the AVIP program. The views expressed in my testimony are my personal views and not meant to be taken as those of the DOD, Air Force, Air National Guard or my command.

As a military member since 1979, I was raised in a family of military service, with my Grand Father serving in WWI and my father serving during the Korean conflict as a Marine Fighter Pilot. I joined Marine Corps in 1979, following in my father's footsteps and am continuing to serve my country in the Air National Guard.

In my opinion, one of the biggest challenges to the success of the AVIP program is understanding all of the issues and perceptions that exist out there. Even those perceptions that do not follow the party line. I feel that if commanders and senior leadership do not understand the intricacies of the issues that have arisen over the Anthrax Vaccine they will be ill-equipped to meet the concerns raised by the field. Accurate, consistent, non-conflicting information is the key. In my research to enhance my knowledge and understanding of these issues I have come across two areas that concern me greatly. First, there appears to be a perception in the field that they are "NOT" being given accurate, consistent, information on the Vaccine, to include its safety and efficacy, and as a result they are losing or in some cases have lost their trust in the DOD. Second, this perception or lack of trust may be impacting our force readiness. The following is provided in hopes that the committee can better understand and fully appreciate these two significant challenges that I feel we face today.

Before proceeding I would like to offer my view of those who serve in the Military today as I believe this is a key element meeting the challenges cited above. There is no doubt in my mind that those volunteers who serve their country today are the most educated and best trained in our country's history. They are trained and qualified to work, maintain and employ some of the world's most sophisticated equipment in the most demanding of environments. They are taught such things as risk management, Ethics, Law of Armed Conflict and the importance of Accountability.

Acknowledged:

- The threat of a BW attack of Anthrax has existed since 1990.
- There is a vaccine available that either by itself or in conjunction with Chemical Warfare gear and/or post antibiotic treatment should significantly increase one's survival rate if subjected to an anthrax attack.

Concern:

- Ancedotal evidence indicates the reaction rate to AVA exceeds the product insert and what the field is being told.
- Ancedotal evidence shows the AVA is at least temporally associated with systemic reactions, hospitalization, cardiac events, and symptoms similar to GWI.
- The Anthrax Vaccine may not be completely safe, based upon above concerns and/or due to improper manufacturing procedures identified by the FDA and testified to by the GAO.

Examples that I feel are fueling the perception that the field is not being given consistent, upfront, accurate information.

- Dr. Burrows conducts review of the AVIP program as directed by the Sec of Defense.

- Dr. Burrows declines to testify to the Subcommittee, stating that the Defense Department was looking for someone to review the program in general and make suggestions, and I accepted out of patriotism. He acknowledges that he is not an expert on Anthrax.

- DOD has stated "This vaccine has been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers."
- LtCol Hall, in his ANG brief, Countering the Anthrax Threat, April 99, in response to the question: Do all farmers or veterinarians ROUTINELY receive anthrax immunizations? No, they do not. This is an unfortunate misconception perpetuated by misrepresentation in the DoD Anthrax Vaccine Program brochure.
- On 9 July 99, I picked up a Anthrax Vaccine Program from an Active Duty installation and it still had the statement, "This vaccine has been safely and routinely administered in the United States to veterinarians, laboratory workers, and livestock handlers."

- The AVA Product insert states; "Systemic Reactions: Systemic reactions which occur in fewer than 0.2 per cent of recipients have been characterized by malaise and lassitude. Chills and fever have been reported in only a few cases. In such instances, immunization should be discontinued." (0.2% that is 2 out of 1,000)
- The "Safety" of the Vaccine has been sold on this 0.2% reaction rate.
    - DOD web page, Major Strawder's radio interview ABC News, Environmental impact assessment for MBPI, Dr Myers testimony to House Subcommittee on 9 April 99.
- Korean, Trippler, and Ft. Bragg studies indicate higher systemic reaction rates. (100 times the product insert in some cases) This begs the question as to why and how does this relate to the safety of the Vaccine.

- Statement: There has never been any reported long term reactions from the Vaccine.
- True: However the GAO in testimony stated that long-term safety of the vaccine has never been studied.

- Field perceives actual reaction rates exceed 0.2%
- For example, the experiences at Dover AFB and Battle Creek MI

- DOD reports adverse reactions rates are below 0.2%:
- Dr Sue Baily, Defense Link news 24 June 99, 0.01% of the shots caused an adverse reaction.
- Gen. Roadman, USAF online News, from talk to Dover personnel, less than 60 adverse reactions or .007% have been reported to FDA
- Mr. Bacon's remarks in response to the letter of indemnification. The adverse reaction rate is a minuscule .009%. 79 adverse reactions out of nearly 900,000 shots given so far.
- The reactions from this vaccine are less than vaccines we give to children.
- I am still seeking a definition as to what an "adverse reaction" really is.

- The VAERS reporting system used to substantiate the above low rates is being perceived as not being impartial.
- FDA requests and encourages VAERS reports on all reactions, even those that are only temporally associated with vaccines.
- AVIP program filters VAERS system
    - Requires the reporting of events that only result in Hospitalization or 24 hours loss of duty
    - AVIP requires recording Severe Local Reaction and Systemic reactions in medical records, but directs that these will not be reported unless contamination of lot is suspected
    - VAERS form does not go directly to the FDA, it is reviewed once more prior to reaching the FDA.
    - This filtering has one tremendous down side. It does not allow for the identification of less severe reactions (which may indicate a problem) that may be occurring in large numbers across the population.
- Also, there is No DOD position on when or how to deal with people who cannot continue with the vaccine
- You can court-martial the refuser, but what do you do with the person who cannot medically take the shot?

- The public recently learned that the Secretary of the Army granted indemnification to the Anthrax vaccine manufacturer in 1998. The DOD states that this is a normal procedure to reduce the insurance costs to the company.
- A Pentagon spokesperson is reported in paper as saying that the last time an indemnification was given for a vaccine was in 1976 for the swine flu vaccine.
- Next, a Letter of indemnification appears on the WEB, signed in 1991 by the Secretary of the Army granting indemnification to PRI for the production of Anthrax Vaccine to be shipped to MDPH, where MDPH was to bottle, label and test.
- This indemnification states: "The obligation assumed by PRI under this contract involves unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the anthrax vaccine. These concerns stem from: a) the limited use of the vaccine to date, i.e., tests prior to approval of a vaccine by the Food and Drug Administration are on too small a scale to permit accurate assessments of the types and severity of adverse reactions (only widespread use can provide this assessment); and b) insufficient experience in mass immunization programs to truly evaluate the efficacy of the vaccine. Moreover, there is no way to predict whether the pathogen against which the vaccine may be used will be sufficiently similar to the pathogen used in tests to ensure vaccine

efficacy."
- How does a health care worker or commander respond to this when presented it by a troop?
- Unfortunately, accurate Vaccine records identifying the approximately 150,000 individuals vaccinated during the Gulf War with AVA do not exist.

- There is a transcribed copy of the FDA inspection into the Anthrax facility that is available on the WEB. The write-ups by the FDA do not instill confidence in the production procedures. Would it not have been better to tell the field this up front instead of having them find it out on some WEB site?

- I have been told by people that reactions, that may be related to AVA are not reported by recipients to medical personnel due to a perceived threat of retaliation, i.e. being labeled a trouble maker or being removed from duty status

- Based upon what I have been told, I believe there exists a perception that:
- Anyone who questions the safety of the vaccine is labeled a "Nay Sayer" or troublemaker.
- The medical community and command are not sensitive to people who report reactions: I was told: "The two things I know about the anthrax vaccine, first, if I have a bad reaction the military will not admit it is due to the anthrax vaccine, second, they will not take care of me."
- If you are having a reaction it is better to hide it than come forward.
- People are tired of hearing military medics say, "We do not know why this is happening to you but we know it is not due to the Anthrax shot" and
- People are alarmed when they hear a medic say, "I can't say for sure that AVA did not cause your condition, but since I cannot say for sure that it did, I must recommend that you continue with the vaccine."

I have read that this vaccine's systemic reactions are no worse than those of Hepatitis A, Oral Typhoid, or other vaccines. This may be true, but is the question not how does this vaccine's reactions rates compare to others, but rather are the actual reaction rates in line with the expected rates and types for which the FDA licensed it?

Even if the above issues raised do not actually effect the safety and efficacy I would offer that there are enough people in the field who perceive that the safety and efficacy of the AVA is in question. Meeting the challenge that this perception offers will require, in my opinion, first an acknowledgement that these concerns exist, followed by open and honest communication to alleviate those issues that are raised.

Some people say, "The Benefit outweighs the Risk." My only question to this and hopefully the committee can eventually provide an answer, is; what exactly is the Risk? My first impression of the vaccine side effects were those stated in the product insert and quoted by numerous officials. Are those the risks? Or is the risk ending up like those individuals that have previously testified before the committee and those testifying here today, assuming the anthrax vaccine is the cause of their aliments? Finally, will this yet undefined risk increase or decrease over time as the number of those vaccinated increase thereby increasing our database.

GREATEST FEARS

- AVA, a potentially valuable force protection tool, may not be available (AVIP program killed by congress) due to poor communication i.e.
- Field perceives that they are not provided the whole story.

Force readiness is being compromised, the TRUST ISSUE. The following are some of the effects that the AVA program appears to be having on retention. I would offer that those leaving over this have made a Benefit outweighs the Risk assessment and their version is the RISK does outweigh the Benefits.

Dover AFB:

- 6 aircrew remain DNIF (duty not including flying) since receiving AVA cause still undetermined
- 24 others being worked up at Walter Reed since receiving AVA, cause still undetermined
- Potentially others not reporting medical conditions due to fear of retribution or loss of duty status
- Supposedly 30-40% of the aircrew (Pilots, Flight Engineers, Load masters) from reserve Sq. have or intend to resign vice take the vaccine.

Connecticut ANG:

- 8 pilots forced to resign after they refused to take AVA. NOTE: some of these pilots were part of an information gathering team directed by the Commander. They refused to take the vaccine after the issues raised in their research could not be answered.

Wisconsin Air National Guard:

- Story ran in Madison Newspapers, INC. June 19 1999, at least 6 pilots are expected to refuse the vaccine. Note: one was in line to be the next Squadron Commander.

Travis AFB:

- 17 KC-10 tanker aircrew resign from the 79th Jan-Apr 1999
- 31 Pilots out of the 301st have submitted resignations, # expected to climb to over 60% by end FY 99
- 429 years of flying experience lost.

- I am told an IG complaint is pending due to an individual's 1288 reflecting job conflict as reason for leaving vice AVA
- Note: I am told that due to funding issues in the reserves 1288's are not processed until the end of the FY

From the above it appears that before units are even leaving to enter the theater where Anthrax may or may not be used, their combat readiness is being compromised, in some cases potentially by as much as by 50%

IMPORTANT NOTE: People are not leaving because they read some article on the "Dark side of the Web." They are leaving because they are seeing people, with whom they have served for years and in some cases combat, take the vaccine, become ill and no reason given as to why, other than we know it is not the vaccine. To the end, those with whom I have talked, state that they are leaving because of the vaccine and that they have lost their trust in their leaders.

In closing, I would ask not only the committee, but those commanders who read and hear this testimony to take a honest look at the AVIP program, the issues raised above and those being raised in the field. My purpose in testifying here today is not to kill the AVIP program; quite the opposite. I welcome a vaccine that would protect not only myself but those whom I am entrusted to lead into battle, provided it is truly safe and effective. It troubles me deeply to watch outstanding service members leave in the fashion that they are. Finally, it would be irresponsible of me, as both an American citizen and military officer, had I chosen the easy path and declined your offer to testify here today.

Attached is a list of comments by service members with regard to the Anthrax Vaccine. This list has been compiled by those actively involved in the AVIP issue and was provided to me for information. I make no endorsement of the positions expressed in this attachment. I ask that this attachment be included in this testimony for the purpose of providing the committee examples of what is being said and exchanged out there in the field. I do not intend for these comments to fuel some form of hysteria, but rather I hope to enlighten those involved in the implementation and review of the AVIP program. I feel commanders need to be aware of what is actually out there, so that they can deal with this issue from a position of knowledge and compassion. Hopefully, these comments will aid the committee in its evaluation of the program and possible recommendations to alleviate these feelings of concern and or doubt.

INTEGRITY BEGETS LOYALITY; LOYALITY DOES NOT BEGET INTEGRITY

ATTACHMENT 1

FEEDBACK FROM TROOPS AND CONCERNED PARENTS

ON THE MILITARY'S MANDATORY

ANTHRAX VACCINATION IMMUNIZATION PROGRAM (AVIP)

(Excerpts from e-mails and letters over the last year shared between individuals and with key citizens concerned about the policy)

From a young woman in the Air Force.... "There are quite a few people here who claim they've had reactions (and I've seen a few of the rashes--not too pretty)."

24-year-old Airman (male)... "I already had mine from lot FAV020 and have been sick ever since."

Wife whose husband is stationed at NAS Oceana... "Last Wednesday when he got to work they sent him to get the shot. No warning or anything. He only has 9 months left in the Navy."

Service member with adverse reactions. . . "I have had two shots. Six days after my second shot, I experienced severe nausea and cramps. When I would lay down in bed, I would also get severe dizziness. The ringing in my ears was so loud that I had to tune it out to go to sleep. The nausea symptoms only lasted a day, the dizziness lasted about three weeks and the ringing went for a couple of months. It has been 3 1/2 months since my second shot and all of the symptoms are gone. We are now being forced in my reserve unit to get the third shot. I will not."

Same member. . . "I know of at least two other individuals in my unit who are sick. The first is probably the worst that I have ever heard of. The last time he went to the emergency room for another one of his "episodes" the doctor said that he looked like a 90 year old man. He will never fly again, and at this point will probably never drive either. His wife is afraid that he will slip into a coma and die."

Wife whose husband is in the US Navy.... "My husband took his first shot 1 1/2 weeks ago. Since then he has had a headache, fatigue, tightness in his chest and his left arm feels weak. The doctor told him that if he doesn't feel better that they would run tests to see if it is affecting his liver or kidneys."

Service Member (male).... "I personally began feeling effects after the first shot, however, blamed them on stress. I can tell you after 4 shots and many medical visits later it has only gotten worse. I have 14 years of service and am prepared to give that up if we are unable to somehow persuade them to put a stop to the program."

Air Force member. . . "Let me get this straight. The Pentagon has determined it's in our best war fighting interest to announce to any potential enemy that our people are vaccinated against anthrax? I feel so much safer now that our leadership has telegraphed our defensive liability to the enemy. This is so asinine I can't believe our congressional leaders are letting them get away with this."

Service member (female)... "I acted on blind faith in the Department of Defense, my superior and trusted individuals I felt were qualified to administer the vaccine. Following the first two shots of the series I noticed that I was extremely fatigued and nauseous... the third inoculation not only enhanced the same symptoms but I also noticed that I was becoming increasingly short tempered emotionally, nauseous, experienced loss of appetite, and achy joints... I started to feel ill, chills, fever, and nausea. My symptoms had increased to include headache, dizziness, diarrhea, and abdominal pain."

US Army (husband and wife)... "My wife and I are currently on active duty in the US Army. Recently, while serving in Korea, we were vaccinated against Anthrax. Unknown to us, my wife was pregnant. It is highly likely that she conceived between the 1st and 2nd vaccinations in the series, but I do not know for sure. In any case, she received 3 sots prior to determination that she was pregnant. This month she delivered a baby girl at 7 months. Our daughter had TRISOMY 13 and lived for approximately 2 hours before dying."

Young man in the Navy… "To all those who believe please pray for my mom. She has recently become ill and the struggle [against my having to take the shot] is making her weaker. She can be e-mailed at -----. Just let her know she is not alone. Sometimes the running around the politicians' give her gets her really frustrated. Please pray for my mother."

Disillusioned Air Force member. . . "Another good policy is 'trust, but verify'. Quite frankly, my trust has been eroded to practically non-existent. It is unreasonable to expect trust in light of the government history of repeated, and illegal, (according to international law) experimentation using U.S. military personnel and other citizens. When their official press releases and brochures contain such gross misrepresentations and distortions of facts, trust is impossible."

Another young man in the Navy… " We are the young men and women of the United States Armed Forces protecting what allows us to take a stand. They tell me that I protect the Constitution but I am not protected by it. As an Afro-American, I love America and I know America loves me, but there are some people with other motives in mind, mostly money, and they are the ones that American should take to Court Martial."

Young man in the US Marine Corps regarding a court martial…. "the WORST punishment they will receive if it is a special court martial, which is probably is, would be reduction to private, , 180 days in the brig, forfeiture of 2/3 of their pay for 6 months, and a bad conduct discharge, which is equivalent to a felony in the civilian community."

Young lady in the US Army requesting information… "Anything you have would be greatly appreciated. You can not imagine how much this means to me."

Mother of a US Marine… "My son has never harmed anyone in his 22 years of life. He has not given his father or me a moment's grief and we set high standards for our children. He does not drink, smoke or do drugs. He does not put poisons in his body and he doesn't want the marines injecting him with any."

Father of a son discharged from the Navy for his refusal… "With Clinton's shenanigans in the White House, the Chinese stealing our nuclear secrets, the daily dosage of crime, mayhem and trash in the media, we believe that few employers would care too much about a discharge which resulted from a young guy simply attempting to protect his health."

Mother of son in US Navy…. "We already wrote to Senator Richard Durbin, in March, we never head back from him. We already wrote to Senator Peter Fitzgerald, he replied saying there is nothing he can do to help us with the Anthrax topic."

Young man in the US Navy… "I have less than 70 days left and cannot see why I should start the shots. I won't be on active duty to receive the full series. I am also concerned because many of my fellow service members are getting sick from these shots."

Wife of a Marine… "He says his arm feels like it got punched real hard. He did tell me that some other guys had some weird stuff."

Service Member/Male…. "The only thing I am really allowed to say is that I am very concerned with the vaccine and the fact I was ordered to take it. I have submitted a memo with several questions and am waiting for a reply."

Gulf War Vet… "I will probably die eventually from this stuff….I can live with that idea… I did sign away to do all that was necessary to protect the freedom that I want my children to have… but I didn't expect to bring something home and give it to them!

Wife of a Gulf War Vet… "What, is there anyone out there who even gives a damn anymore."

Service Member/Navy…. "My question is that if this had a low volume, then what other kind of junk

was in there??? Formaldehyde???"

Service Member.... "I would die for our great country in combat but not from some vaccine."

Wife of service member.... "He's been in misery for 9 months now, and now has this garbage (Anthrax vaccine) in his system also taking its toll. The whole thing makes me so darn mad, too! I just want to scream whenever I think what our government is doing to it's people."

Mother of a son in the Navy.... "What the hell is happening? I told my son under no circumstances to take the shot. He knows that his father and I are behind him 100%."

Mother's son punished for refusing.... "Both these men were punished by being worked 7 days a week...16 hr., Monday-Saturday and 12 on Sunday. Both men had a reduction in rank, all hazard pay that was given for this mission was taken out of their pay (about $1,300 for my son) and both of them were given menial jobs. My son had to fill sandbags and keep the mess tent tidy. His usual job is launching planes and repairing the hydraulics."

Young man in the Navy.... "Last night I got my first anthrax shot. Got the shot in my left tricep. My arm has hurt all night long. I've also had lots of tingling down to my toes. For the past couple of hours my stomach has been upset and my had all cloudy. Almost like I've got yellow fever symptoms."

Objecting Air Force member. . . "if they had been producing baby food, instead of government-contract vaccine, the FDA would have shut them down hard. Their inventory would have been impounded, and a massive recall made of all their products. Lawyers would be celebrating in the streets."

Wife of a service member.... "I don't know what to say - I'm just scared to death for him and our family."

Wife of a service member/Navy.... "My husband is also on the Roosevelt and has been forced to take his first Anthrax shot. This concerns me a great deal. My concern is more for the long term. This whole issue is just an outrage to me! I really don't understand how the military can get away with this, especially after the Gulf War."

Sick Gulf War Vet... "DO NOT TAKE THE SHOTS. You can always get a different job but when your health is gone YOU HAVE NOTHING. If I knew what would happen to me (healthwise) I would of told them to kiss my ass and court martial me or whatever they wanted to do."

Wife of Service Member.... "My husband will be getting the anthrax shot pretty soon, I want to prevent that any nay cost. I heard people can be waived if they belong to certain religious groups. I am willing to try any new religion to prevent my husband from getting the anthrax vaccine."

Mother of service member/Navy.... "My son is aboard the USS Abraham deployed to the Persian Gulf. He was forced to take three (so far) Anthrax shots, out of lot FAV030 as it turned out. I tried to stop them from vaccinating him but was stalled by the Navy, even my congressman's office had notified them that he had severe allergic reactions in the past following school vacations. They (the Navy) put us off till they were between satellites and (began) vaccinating everyone. I became so angry that they had NO regard whatsoever for his health."

Unconvinced service member. . . "Congress and Americans need to understand that we in the military have little to zero faith in our leadership concerning the anthrax issue. When DOD claims there is a lot of misinformation on the Internet concerning anthrax, they are absolutely right, and it's on their website!"

Son's e-mail to mother... "I couldn't send or receive e-mail for a while because we were between 2 satellites. I'm sorry Mom, I took the shot. In fact, almost all of the most informed and outspoken people that didn't want it got it. I was under duress, I couldn't afford the consequences...the short term ones or in my career after the military... I feel like I let them rape me with a needle."

Letter from concerned service member. . . "It is amazing to me how little most of the docs know about this vaccine, its history of manufacture, or anything else beyond the basic med school stuff, and 'the party line' repeated by the senior medical staff. I don't understand how so many smart guys can be so disinterested as to not even do any independent reading on the subject. Where is the critical thinking? Don't they have a moral, ethical, and professional obligation to question the scientific validity & methodology used?"

Gulf War Vet.... "I'm 29 years old and for no apparent reason, my body is falling apart. For the past several years I've had general soreness in all my joints and muscles. However, over the last year, year and a half it has gotten worse. I have muscles on my body that will burn off and on for months with no apparent reason."

Service Member.... "I like the military. I think it is great. But there is nothing keeping me here now... especially with something to this nature going on."

USMC.... "so it doesn't mater if you have 18 months left or not you will get it anyway. I have about 15 months left and they are planning on giving it (anthrax vaccine) to me. There is something very wrong here. I don't want that shot. I know others that feel the same way but they don't want to risk their careers. I can only hope that someone will help us quick.

Service Member/Navy (letter to Congressman_____).... "I request your assistance to have the military rescind the mandatory requirement for all service members to receive the Anthrax vaccination."

Reserve Component Helicopter Pilot. . . "The mission is extremely demanding, and the ____ is a systems-intense aircraft. The list of currency items is very long. We demand a high level of regular participation from all of our crew, hence the requirement to live in the local commuting area. This is a half-time job for our aircrew, on top of their 'real' full-time one. The old days, where a couple of flights a month kept guys proficient, are long dead and gone. We cannot afford to be driving away instructor and evaluator pilots by placing the last straw on their back. That kind of experience can't be bought."

Father of son in Navy.... "Parents should be audacious, brazen, and impudent. I personally do not believe that the majority of republicans, democrats, etc. care about our children. They care only about their fannies. They may translate this concern into lost votes."

Husband & Wife both in US Army.... "My wife and I are both active army that recently refused the anthrax vaccine. The amount of pressure exerted on us as punishment dealt out has been overwhelming. My wife had proceedings started on a general court martial and I was threatened with the same. This is after being threatened with physical violence to restrain and forcibly inoculate us. I am scared to death! I am scared for our future and thoroughly disenchanted with our military. After being pressured for several days with these threats of prison for myself and my wife under conditions including sleep and food deprivation we relented. I would risk dishonorable discharge but couldn't bear to see my wife in prison. What is happening to this country?"

US Navy Airman.... "I've made my decision. I have decided to refuse the anthrax vaccination. I hope God is on my side."

US Marine.... "I'm getting out in 4 months so I won't get it but I don't think it is a good idea. They can tell you its one thing and give you another; its happened before."

Young man in the Navy.... "I like the military so far (I've been in one year). At the end of a newspaper

article about the resignation of some pilots it said a study was commissioned to find out what people thought about the vaccine. Well, I guess they didn't ask anybody in my squadron. The article said a dozen people the country complained about it, I know a dozen people personally who flat out refuse to take it. I'm sure the threats from the higher-ups will be pretty severe and cause some people to crack!"

Service Member…. "However, I wanted it to be understood and documented that I was not taking it voluntarily and that I was doing it only under the threat of disciplinary action, so that if and when I get sick from the anthrax series, the government couldn't say I agreed to be part of a test group. I created a document saying just that, brought it into my commander, and he would not sign it. We have been threatened, belittled, and lied to by several members of our "higher ups" all for simply asking for some kind of documentation stating that it is mandatory and we'll face disciplinary action if we refuse."

Pilot. . . "Interestingly, the half of the squadron which was called up to support the latest military adventurism are not receiving their shots, even though they are overseas, on active duty."

US Marine…. "I have to thank you for being so concerned about a total stranger. It means a lot to have support from an unexpected source. It makes me sick that 2.4 million of the country's finest are being used as guinea pigs as a result of monetary greed. Who is to say the vaccination Mr. Cohen received was an anthrax vaccine? It could have been a flu shot for all we know. The biggest dilemma in my eyes is the effect on any children I'm planning on having. Are they going to care for my child if it has a physical deformity or mentally retarded? Are they going to take my daily grief away from me? The fact that I'll have to look the child in the eyes every day knowing that it's lifelong misery is due to political greed. I honestly love being a Marine. I used to take pride in it."

Mother of USMC… "I want to call every parent of a child that is capable of enlisting in the military and tell them not to let their child do it! I think the President should get it himself and his family."

Mother to son in the Navy… "I was shocked to discover that his hair is suddenly very thin on the top back of his head. He has had three anthrax shots. Also, he has been getting stomachaches, something he never did before and a bad headache, not constantly, but every few weeks. He is only 22, and I haven idea why his hair would be thinning as he always had extremely thick hair. He also had some rashes."

Mother of USMC…. "The Lt. asked if all questions were answered to everyone's satisfaction. The answer was a resounding NO. At this point he assured everyone that a better-informed corpsman would be brought in to answer their questions. Today he informed the marines that a corpsman could not be located to speak but if anyone is interested in an "easy out" he may refuse the vaccine and be given a Dishonorable Discharge. I am amazed at the number of military people who have refused the vaccine and how blatantly the issue is ignored by the powers that be."

Father of US Marine… "Even if he gets the shots, I intend to stay active in this fight against this corrupt system. It is wrong to do this to our kids. We, the people, have to stop this tyranny and I'm willing to stand along side anyone else who feels the same."

AF Reserve pilot . . . "The effect this anthrax shot is having on wing's morale is crushing."

Mother to a US Marine…. "To get discharged they have to get 3 NJPs that's what our son told us. I think everyone makes up their own rules. What a system we have. My husband, this morning, took all the signs down in the store for recruiting in the military. He said until they change their ways he will not have another sign in our store. We have been here for 19 years and there have always been signs in here."

Service Member…. "I don't really care and if its that big of a deal, you can refuse it and they will take some of your rank, but I'd rather have a little rank taken than have to deal with that shot for the rest of my life."

Young woman in the Navy… "I'm very scared. I am young and want to have kids one day."

Young woman in Air Force.... "I am supposed to get the vaccination on Wednesday and am going to refuse. The flight doctor pretty much said that "this" isn't worth ending your military career over... I had to disagree. He couldn't really answer any of my most concerning questions. This one (shot) is different and it isn't necessary."

Young man in the Military.... "I have my military career in one hand and my life in the other. I am firm on my decision not to take the shot."

Young man in the Reserves... "I think it will take the Mass-Exodus of reservists to get peoples' attention on this issue and guess what, it's coming."

Military Member (female).... "I have been in the military for 13 years and I have been very dedicated until now. I have a six-month-old son and I am nursing him. I was told that I had to have this anthrax vaccine. I have called several veterinarians (the military says they are routinely inoculated) and I have not been able to find one yet that says he/she has had the shot. I am also put off by the fact that our commander in chief, Clinton, refuses to get the shots."

USMC.... "The Corpsman claimed to not have the Lot numbers readily available."

Air Force Member.... (I'll take the shot?) "When the Department of Defense starts answering such questions as: Why do hundreds of Gulf War Vets have "squalene" in their blood?, Why are bad reactions to the shot by Gulf War veterans not well documented? Is the vaccine being given to our troops the exact same vaccine that was licensed by the FDA?"

Father of USMC.... "Question: Are they giving the same dose to 110 lbs. females as they do to 200 lb. males? So is this why there is a 45% adverse reaction in the women, more so than the men?"

Philosophical service member. . . "We should have a doctrine that states "Biological warfare is UNACCEPTABLE."

Gulf War Vet...."I too was willing to die for my country... I went to a war and came home sick... now my family has it too."

Aviator trying to lighten up the discussion. . . "There will be many more battles ahead on this issue, and we don't want to be on the wrong side of the war when it is over. As Mick Jagger once said, "time is on our side." (Mick is not a military historian, but he did add a lot to the Vietnam War.)"

24-year-old Army Reservist.... "Right now in order to avoid all the legal hassle I'm planning on getting out of the reserves starting this month in order to avoid all the legal hassles. I for one am outraged that anyone can say, "shut up and follow orders" in the face of the overwhelming evidence that the government is doing serious harm to its troops. I love the Army and every time I wear that uniform I wear it with great pride. I also follow all legal orders to the best of my ability, but I am not a blind lemming who will obey what may very likely turn out to be, and what I consider to be, an illegal order."

Disillusioned Officer. . . "'Get your shot or get out.' I have heard that rhetoric before in my short career. 'Take this assignment or get out,' 'Deploy over 270 days a year or get out.' Well, during that time we have lost some great pilots and patriots. They became tired of our leaders not dealing with the problems."

Mother of USMC... "I called Blood Services here today and found out it takes 6-8 weeks for your body to get the blood made back from a donation. He also said he would not recommend anyone taking any vaccinations of any kind right after giving blood. He said none of the guys at Yuma who gave blood should have the 3rd shot."

Officer in Air National Guard... "The only advice that I can give is very personal. No matter the punishment, I would refuse based on the evidence that does not exist in regards to safety and efficacy."

Current Service Member…. "If there is something embarrassing or some criminal wrong doing that they're trying to hide, they need to fess up and put forth the individuals responsible to face the music no matter how high up they are in the government."

Young woman in Air Force… "I have expressed my concern, but I don't think they are really taking me seriously yet. I have been in about six years. Crazy how it has to come down to this. I think it is their loss, though. I have written my congressman and my mother has as well. I got only a short generic response back so far, so I am thinking of writing again."

Young woman in the Navy… "How can I trust a government that admitted to conducting secret experiments on military personnel in the past? Had I known when I was a civilian that I could be injected with experimental chemicals and medicines without my consent, I would not have joined."

USMC in Okinawa… "I e-mailed my Congressman but he hasn't e-mailed me back. I was wondering if you could help?"

Wife to young man in the Navy… "My husband is assigned to the USS Roosevelt and has refused the vaccine. I know they have been playing mind games with a lot of the guys and have been making a lot of threats. I did talk to a JAG officer in Washington DC. He compared it to the fact that "if they were told to get a haircut, and they didn't get their hair cut, the would be punished. Then a month later they were told to get a haircut, and they didn't they could be punished once again." To compare getting a haircut to something of this magnitude is incredible.

Media contact…. "It is outrageous and pathetic what is happening on this issue. Keep up the efforts."

Former Marine… "It is still believed by many thousands of people that the military is covering up something about the so-called Persian Gulf War Syndrome. The military denies everything (publicly) and yet we see so much evidence."

Pilot. . . "I think the whole anthrax dilemma comes down to one very basic issue…TRUST. There is no trust when it comes to how this vaccination program has been "sold" to the military. If anthrax is such a threat, what isn't the DOD telling us that we need to know? I just don't buy into their sales job."

Law School Attorney…. "These gallant Marines must do what their conscience tells them to do."

Former Air Force Member…. "ALL ORDERS ARE NOT LAWFUL! Look back at the My Lai Massacre in 1968 and to Nuremberg in the 40's."

Air National Guard Pilot… "My meetings with my Senator's liaisons went poorly as well."

Gulf War Vet… "I never felt so sick. I was bedridden for a week like many of my colleagues who got the shots. I had high fevers, head and body pain and fatigue so bad I couldn't walk. I couldn't move the leg where the injection was given. I had never been so sick in my life."

Air reservist concerned about health coverage. . . "I called my insurance company (AETNA) last week to ask about adverse reactions to anthrax. Would I be covered if I required any medical treatment, long or short term? The answer was an unequivocal 'NO.' I refuse to put my civilian job at unnecessary risk, my health, or my future children's health for that matter for a vaccine that hasn't been proven safe or for a threat that doesn't exist in sufficient probability to warrant this program."

Concerned parent… "Physicians who are my friends have told me there is not enough data to establish the efficacy of the vaccination. They also say it sounds as if the military is executing a "massive experiment."

Air Force officer. . . "A highly respected retired flight surgeon down at Homestead recommends against it, and all the flight surgeons at the Alabama guard said they would get out if pressed."

Mother to son formerly in the Navy… "My son was forced to get the shot in 1998 even though he only had four months left to his tour of duty in the Navy."

Active Duty Servicemember. . . "Well this confirms my worst nightmare. The troops don't mean anything to them. It's all written in profit margins. Find a copy of the old Pentagon Papers. This is nothing more than troop reduction and the abuse of power. This is a sad day when the Boss's of the Worlds Greatest Military defends a lie over the truth. The Bigger the lie more people would believe it - Adolph Hitler... What's missing from this picture? Well, there are some folks not falling for it and I salute you all."

Mother to son in Navy…. "We all know that the captain has stated he will keep putting my son back on restriction until he gives in and takes the shot. So that basically means that my son will be allowed no legal counsel, period. I don't know what to do from here. My son had begun receiving threats and was concerned for his safety when I spoke with him on Saturday."

Grandmother to Naval Grandson…. "My grandson called a little while ago. Said things were not good on ship. Also there have been new verbal threats against him implying physical harm. This feeling of helplessness is what every jack man that thought the vaccine up should feel."

Air National Guard Member… "Our ANG Unit is planning on beginning Anthrax vaccinations as early as this coming August. Any info you would have on this vaccination would be appreciated."

Officer LTJG USN…. "Hopefully some of them (commanders) will listen to the voices of reason and work to help you. Understand that most CO's are receiving all their info from the DoD and therefore do not fully realize the extent of problems emerging. Stay strong and remember that in seeking the truth you are an honor to the uniform you wear, never a disgrace."

Mother of US Marine…. "I am afraid I have no advice for this poor woman, I myself am at a loss of what to do. Can anyone help her?"

Mother of young man in the Navy who refused anthrax vaccine…. "The captain is hunting for the friend who has been helping my son. Lord, I feel like he is a prisoner of war and being slowly, mentally, and physically abused. He pulled a 38-hour shift, two hours sleep and collapsed. They are altering his records and pulling his list of accomplishments. I am beginning to even more fear for his safety and am worried that his captain may not be mentally competent. So far no help from our congressmen."

Military Veteran…. "I have a 10-year-old son to prove something was wrong with one of my GG shots. Yeah, you are absolutely right, there is no doubt at least in my mind that something is wrong with the Anthrax vaccine."

US Naval personnel….. " I have less than 70 days left and cannot see why I should start the shots. I won't be on active duty to receive the full series. I highly doubt that they are going to pay to fly me to a base to continue receiving the shots once I'm a civilian again. I was told that I won't get my Separation Leave until I get the shot. I feel that I am being threatened with this. I am also concerned because many of my fellow service members are getting sick from these shots."

Airman's Mom quotes General Schwartzkopf…"The fight, as many of my fellow survivors will agree, takes careful research, rapid planning and most importantly, the courage to begin the fight. My son is presently an Anthrax Refuser for a multitude of intelligent reasons. His father and I are very proud of his courage."

Mother of a young woman sick from the anthrax vaccination…. "I personally feel that EVERYONE should get out of the military. My husband was in Vietnam and exposed to Agent Orange on a daily basis. However, according to his military record, he was NEVER THERE! Peculiar, huh?"

Concerned pilot. . . . "15 out of 18 F-18 pilots at Carswell will get out if they have to take the shots, most are combat veterans."

Concerned citizen and well-known music personality… "I am truly sorry to hear about your son and hope and pray that he will have a full recovery. The truth of the matter is that we have allowed some bad people to gain access to the highest office in the land. He is the worst thing that has happened to America in my lifetime. We will be generations undoing the harm that this president has done. I pray to God that the next person who becomes our president will have had some military experience and some morals."

Close friend of a US Marine…. "He said he was given several pills to take. He asked the corpsman what it was for and the corpsman said he didn't know but he wasn't taking his, so my friend threw his away also."

Former service member (Army Reserves)… "The whole military, especially the Marines and Army has a "suck it up and drive on" attitude towards injuries and sickness. Many deal with it unless they pass out. Government leadership as they think they can get away with using soldiers as they see fit to use them "for the good of everyone" in their eyes no matter what the cost."

Service member thinking about future implications. . . "For the young LT it means 26 shots just to get him to retirement. Add this to the current schedule and a new LT will possibly have to get 150 or more shots just to get 10 years. That is over 1 a month. Some are good vaccines and proven. The new ones will be our DOD's concoctions. Does this sound smart? Does this sound reasonable? Would you sign up for this?"

Reservist in the Navy… "I am currently a Reservist in the Navy, and have looked into AVIP as much as I could. I know of some fellows who have started the series…. They report maybe a month of diminished libido."

Mother of US Marine… "My son is a Marine in Hawaii and was one of several who held out on getting the Anthrax shots for quite some time; however, pressure was brought to bear and now there is only one lone Marine still resisting (in his unit). Please continue the fight!"

Gulf War Vet… "So we understand how difficult it is for you and allow you to come to your own conclusions; we will respect those conclusions. But after what we have learned, it would be inhumane of us to keep what we know to ourselves."

Mother of former Air Force member…. "My son was saying there are more experimental vaccines to be given to the military…. He said to watch…they will have a type of smallpox scare, to get everyone vaccinated…We will see…"

Anonymous…. "The military is as dangerous to a society as it can be necessary. Just as effectively and swiftly as a military can defend the liberty of a nation, it can take it away."

Father to former Navy service member… "Why mislead the troops into thinking that this vaccine is the 'Be all' and 'End all' of protection? I'm tired of these generals and politicians emphasizing how critical this vaccine is. How many troops will unduly suffer as a result of a misleading representation that this vaccine is the next best thing to sliced bread."

Young woman in the USAF… "I am in the military and there are a lot of people who I work with that have or are experiencing the same problems as some of the ones listed and would like to see the full report (FDA VAERS)."

Naval Officer… "I'm a naval officer stationed at Pearl Harbor. One of my neighbors is currently deployed but talks with his wife on a regular basis. The other day my wife and I were visiting with her

and she was explaining how her husband said one female on his ship said she was concerned about being pregnant and taking the anthrax vaccination. Anyway, they didn't believe her and just figured she was trying to refuse the vaccine. They gave her the shot anyway."

Current service member… "People have to start standing up for their rights and refusal is one of them. The best soldier is an informed soldier--that's my opinion; don't know how the Commander will see it."

Fed up Air Force person. . . "If I hear again that a commander would be unfit if he doesn't give this vaccine protection to his troops, I am going to Puke!"

Current Navy service member…. "I was just told that my separation leave will not be approved until I have taken the vaccine. I just can't justify a vaccine that is being looked at so closely as something that could be potentially dangerous. Can anyone help me out in this matter?? I'm starting to get worried and am not sure what to do…."

USMC in Hawaii…. "My friends did report headaches, nausea, soreness and swelling at the entry site. There were a total of 7 refusers, 2 Marines passed out after being given the shot. After the shot, we had to take a sucker and eat it and wait 15 minutes so we would know any effects. This one Marine was asked by the doctor if he was ok, the patient said no, he wasn't feeling good. He was released anyway. He went to the head and began to vomit. He then passed out on the side of the toilet. My Staff Sergeant pulled him out and he was rushed to the emergency room."

Young Naval man on ship… "I am currently on active duty. I have a large amount of information but I wouldn't mind some press contact if my refusal goes sour."

Wife of husband in the Navy (attended anthrax briefing)…. "They also say that this "vaccine is like a shot gun and will cover the various strain.?!?!?!? They know it is "VERY SAFE: but could offer nothing in the form of documentation to show that the quality issues had been corrected other than to tell me to contact MBPI and ask for the follow up studies on the lots…. HUH???? How could MBPI have done that if the military had the stockpile…"They said people were getting sick but it was independent of the vaccine… it was just a coincidence… and if it was related the numbers were insignificant!!!"

Service member questioning the rationale. . . ."If anthrax is such a threat, civilians probably need to be a lot more worried than a good majority in the military."

Service member…. "I have received the 4th series of the anthrax shot. I will be receiving NO MORE! It takes someone of great courage to stand up for what is true, when those that are elected to do so, do not have a clue! You are all a true inspiration to those that keep the belief that somewhere there is good in this world."

Former USMC recently discharged… "This frightened me because I didn't want my refusal to affect my mother's job as a nurse. The fact that there had been no research into whether the vaccine could cause sterility, birth defects or cancer also worried me."

Wife of Air Force member…. "My husband, who is still active duty… I am out of the service and keeping my fingers and toes crossed the that he will not have to take it before he gets out this September."

President of Veterans organization… "Our chapter is contemplating calling publicly for a suspension of the anthrax vaccine program. In the meantime we have requested our congressional delegation to call for a suspension of the anthrax vaccination program."

Current service member…. "I am currently in the military and have to watch what I say and who I contact about this subject. The only thing I am really allowed to say is that I am very concerned with the vaccine and the fact I was ordered to take it."

Canadian citizen and service member…. "I think you will see by the articles I am sending you, the Canadian Forces is trying to put a spin on the issue by saying that the anthrax vaccine we have is not the stuff the Americans are worried about (ours came from lots with expiration dates in 1999). They are getting us ready for what is coming…."

Angry former servicemember…. "If this is so about the shot of anthrax,… then what Freakin' shot did they give the rest of us and they called it a GG booster? I know what a GG feels like and it sure as hell was not a GG shot. So what was it? If not anthrax? Squalene? Urine? What? Someone please let me know. The United States Government sure as hell does not want us to know what the shot was. I serviced with the… and I am sick. Some answers instead of BS from our government would be nice."

Former service member…. "I hope that the recruitment drops off even more as most of American is finally realizing that this is less the land of the free and more the land of deception."

Current Air Force Member…. "I have 3 weeks remaining before I will be forced to take the series of shots. After 18 years in the Air Force, I must choose shots or retire. Can anyone help point me to where I can find NON-DOD answers."

Mother of a US Marine… "I just spoke with my son. I asked him how he was doing. He said, I'm being railroaded so I guess I'm not so good."

Mother of a US Marine… "Perhaps this 'rebellion' to take the anthrax vaccine will promote further studies to make this safer for the men and women serving our country. They are Americans first, not medical lab rats."

Active Duty Pilot. . . . "One thing I learned is that the DOD has more than once made terrible doctrinal decisions and lied to the soldier. The doctrine of creating a 'biologically resistant warrior' is crap! How much money will we spend to create this resistant warrior?"

Statement from a concerned representative… "In short, this Administration is expecting our servicemen to do one hundred times as much and place their lives at risk one hundred times as often with eight hundred thousand fewer people for as little as six dollars and seventy cents per hour. Mr. Speaker, I recently paid a plumber $90 an hour to unstop my garbage disposal. An auto mechanic can expect $50 an hour. A teenager working as a bagger in a grocery store can earn up to $12 dollars an hour. None of these jobs require 24-hour dedication to duty and a constant threat to life."

Concerned service member. . . "Was there ever a secret project to use squalene in drugs prior to the Gulf War? The Vanity Fair article makes a pretty good case for this, with names, dates, and other sources… I know that this may be sensitive, but it goes back to the troops' inherent lack of trust in the DOD."

Former military member… "Having served in the military as a young man I remember how I used to follow orders without questions and I certainly feel like a fool for doing it. As you see more of the world and experience life, your views mature. The young man says it is a moral issue, so I say why can't he be respected for it? Probably because the military does not want individuals…they want sheep. To the lifer that dedicated his life to the government and now believes all of that gung-ho crap about how the military has to follow certain rules in order to protect our country, I can understand your view...but I strongly disagree with it. It is dangerous to a so-called democracy to blindly follow anything and be punished for not 'obeying'… I SAY GIVE ME TEN INDIVIDUALS LIKE THE SERGEANT IN QUESTION… RATHER THAN TEN THOUSAND BLIND SHEEP… I'LL GO INTO BATTLE WITH THE COURAGEOUS TEN WHO STILL HAVE POSSESSION OF THEIR OWN BRAINS!"

Army member discharged for refusing the vaccine. . . "I was given an order to take this shot. I resisted

and I was reduced from sergeant to specialist, lost some money, and did some extra duty. It is now almost six months after the day I received this punishment. on 22 July 1999 I will be discharged from the army with a general under honorable discharge. I have fought long and hard for this discharge and believe that I will get it upgraded to honorable in the end. I would encourage anyone who questions this shot to research it to no end. You will find what I did if you look hard enough. You will find a government who is willing to lie and abuse the soldiers who defend this country. I encourage each one of you who questions this shot to ask yourself one question. Will the government take responsibility if something happens to you? I know what my answer was. I gave up a ten year career in the army to protect my family and myself. God bless you all. I will reply to anyone who emails me. And I will talk to the press if need be!!!!!!!!!!!! Thank you all from the top to the bottom for your support."

Mr. SHAYS. Well, we have heard some very powerful testimony from five very patriotic members of our country and of our service. We thank you all.

Mr. Terry.

Mr. TERRY. Thank you, Mr. Chairman. Indeed, powerful. Captain Richter, I think all of us up here love our country, and that is why we are here as you have spent 13 years in the military. As I have sat here over the last hour listening to testimony, I think if it was a condition to serve as a Member of Congress we had to take the vaccination, I too would probably take the same path that you are choosing.

Mr. Chairman, our hearings, at least, no pun intended, my exposure to this vaccine has been more on the academic side. We have studied protocol, testing, side effects or what has been tested by the manufacturing process, quality control, and today I think is the first time that we have truly seen the human side, although it has been certainly why you have undertaken this process.

The testimony we have heard here today is powerful, and there are so many areas, so many questions that I want to ask all of you, but I am going to narrow it down into two areas. And, Lieutenant Rovet, I am going to start with you because you are the first one that said it, the first one to ask really the true magnitude of which our service personnel are experiencing symptoms. And you know more than I do in the sense that medicine has become more of a science than an art and that it has to fit into specific pigeonholes and have certain labels placed upon it, and that probably more the discussion, as the lieutenant colonel has said, needs to focus not on hospitalization for 24 hours but just the symptoms that we have heard here today of a variety of different symptoms.

But you said, and Sergeant Soska also said, that probably one of every three have come forward or voiced concerns. And certainly I think that is probably more anecdotal than scientific, the one in three. But why don't you explain and draw out how you were able to base a conclusion that Captain Piel, there's three others out there that are in the same position that have refused to come forward.

The second part of my question is going to be, why have they refused to come forward? But let's talk about, first, how do you base that one in three?

Lt. ROVET. If I understand your question correctly, sir, it's when an individual comes forward and we start seeing what we believe is a trend, we go back and look at some of the symptoms, the symptomatology of what they are presenting with.

My job as a case manager also, I was privy to data throughout the air crew members that were sick for long-term. So I would start looking and saying, well, we have a person here who has a long-term illness who has not been really diagnosed with something concrete. There is no concrete etiology. So we would start drawing conclusions in our mind, or just asking questions, not conclusions. It was more of a hypothesis in the beginning.

And when they came in, we discussed, we listened, and it was opened up to us from the air crew members that there were more people out there experiencing the same side effects.

Mr. TERRY. So these folks have reported some sort of illness, gone to see a doctor, but reported symptoms that weren't necessarily associated to the vaccine?

Lt. ROVET. Right. They were—I know Captain Piel, who was captain at the time, had come forward with problems with balance, what they call labrynthitis or otitis media, and that was originally diagnosed as just strictly a medical problem that we had a concrete etiology on. But also it was the timing relation to the anthrax vaccine and the persistent dizziness that started raising some questions. And then we saw other people coming forward with this timeframe event of the vaccine administration and illness and subsequent no concrete etiology for their illness.

Mr. TERRY. So there is, for these other three folks, there is some medical record that will document an ailment or a symptom?

Lt. ROVET. Yes, sir, there is.

Mr. TERRY. All right. I was concerned when you said, or envisioned when you said that one in three is that three knew they were symptomatic but refused to come forward for fear of some reprisals.

But what we are talking about is that one out of three is not being associated with the vaccine.

Lt. ROVET. Right.

Mr. TERRY. I mean that only one of three is associated.

Lt. ROVET. No. There hasn't been any conclusions drawn in that area yet, but about the fear to come forward, there are some people that have expressed it over the phone that they are afraid to come forward.

Mr. TERRY. All right. So when you testified that there were 30 cases currently and about five or six in the pipeline——

Lt. ROVET. Yes, sir.

Mr. TERRY. First of all, how big of a field are we talking about?

Lt. ROVET. Well, I don't have exact numbers.

Mr. TERRY. Is it 30 out of 300; 30 out of 60?

Lt. ROVET. Right now, out of 1,100 people, a little over 1,100 people at Dover who had been vaccinated, these are what we have now, the number 30.

Mr. TERRY. All right. And then ballpark it based on your earlier testimony there are probably about 90 folks that you think probably have symptoms associated with the vaccine.

Lt. ROVET. Yes, for me to make that leap right now, without scientific data, would probably be incorrect, but as a gut feeling——

Mr. TERRY. Anecdotal based on your experience though.

Lt. ROVET. Yes, sir.

Mr. TERRY. It is a fairly significant percentage.

Lt. ROVET. Yes it is, sir.

Mr. TERRY. Can I have just a couple more minutes?

Mr. SHAYS. Yes.

Mr. TERRY. Captain Piel, I want to start with you. We have heard discussion about reprisal, and we have heard it really in two different categories. One was, as Captain Richter and Lieutenant Colonel Jensen pointed out, is that one reprisal for not taking the vaccination is mandated resignation. But you hinted there may be reprisals for simply even reporting or voicing concern that some of your symptoms may be related to the vaccination.

Can you tell me where you would feel that? How, if you could kind of focus or pinpoint that for me.

Capt. PIEL. Yes, sir. First of all, I would like to say a lot of people don't come forward because they have seen what has happened to the people that were ill and then it become know that it might be possibly due to the vaccine. In other words, they have seen what has become of me in the medical system and they realize——

Mr. TERRY. Called a malingerer, a liar, and those type of things.

Capt. PIEL. And it appears a dead end. So why risk your flying status if you are just suffering some of the mild symptoms of joint pain or you feel a little bit tired. Why should you go to the doctor if you feel you can continue to operate airplanes? And that is why people don't come forward.

As for myself, this whole time period it really didn't seem to matter what the doctor said because I thought it would just be a few more weeks before I felt better. But it became apparent that these comments were starting to erode my character. And I was not being—sometimes I wasn't being examined when I went into the doctor's office.

So that does not encourage one to go try to seek more help from the same individuals that will not, that don't seem to be helping you in the first place. And they dealt with me as if they believed in their office and then sometimes I would hear later that they didn't believe me.

But my commander and others believed me. And I think part of the reason why it is easy for people to believe me in my squadron because many people have felt mild symptoms.

Mr. TERRY. All right.

Sergeant, would you answer that same question: What type of reprisals from reporting, basis of your fears of reprisals, and also from whom. And maybe your opinion of whether you think the reprisals are what I would classify as a malicious nature of trying to—I don't want to use the word cover-up because everybody likes to use that conspiracy-minded terminology—but if you think it is even related to minimizing the impact of side effects from this vaccination.

Sgt. SOSKA. Mr. Terry, I can only tell what I have been seeing with my soldiers.

Mr. TERRY. All right. That is what we want to hear.

Sgt. SOSKA. A lot of the soldiers who are new to the military—I am a career soldier; I have better benefits than they do—if soldiers that are getting married and coming in with family members that have various obligations that they are just struggling to get by to begin with—several of the people, many of the people that went with me to Kuwait during Operation Southern Watch during 1996, we came back and we started cross-talking amongst each other. I guess I was the worst of the group with my condition.

And others started taking notice to that. I have told many, you need to go, you need to get it checked out, you need to do this, you need to do that. Many have listened, many have not.

Many are afraid to come forward, and I kind of feel like the guy being pushed out the door with the door slam shut behind me right now. But, you know, this is me and that is them. I can only do what I feel is right.

Several of the soldiers have—I can tell you for a fact there has been a survey on the web trying to characterize systemic reactions, fibromyalgia and stuff like that they have filled out. And others flat refuse because they are afraid that if they do say something or if their name is used, that it is going to have an impact on their career.

Now, what goes on in their head, I have no idea. But they are afraid to come forward, if that answers the question, sir.

Mr. TERRY. Well, it does. I think the fear is probably real, but part of our job up here is to determine if that is a personal opinion or whether that is a problem in the military. Unfortunately, that may be as tough to decipher as it is scientifically to link these symptoms back to the vaccination.

Appreciate the opportunity, Mr. Chairman.

Mr. SHAYS. Thank you. Mr. Tierney.

Mr. TIERNEY. Thank you, Mr. Chairman.

Mr. Chairman, I want to thank you for having these hearings. They are obviously important, and hopefully we will be able to come to some resolve that will address these issues.

Captain Piel, I wanted to ask you, were there any pre-existing conditions that your doctor suspected you might have had or discussed with you before the vaccination was given?

Capt. PIEL. No, there weren't any.

Mr. TIERNEY. And was there any talk amongst your medical people afterwards that they thought perhaps they had overlooked some, or any conversation about that?

Capt. PIEL. No, there hasn't been any conversation about that to my knowledge.

Mr. TIERNEY. You indicated that you got good support from your chain of command but you felt you didn't get good support from the medical people that you went to. And how does that work on your base? Where do the medical people fall in that chain of command?

Capt. PIEL. Well, they fall outside of—they have their own chain of command on the base. So they don't report to my boss, and he doesn't have anything to do with the medical group either.

Mr. TIERNEY. And that is true all the way to the top of the non-medical people at your base?

Capt. PIEL. Well, I am not sure. I think the medical group falls underneath the wing commander, but other than that, there is nothing—that's where it meets, that's where the operational side meets the medical side.

Mr. TIERNEY. Now your wing commander has been supportive?

Capt. PIEL. Yes, sir, he has, and he has been trying to help me get the right medical treatment.

Mr. TIERNEY. And Lieutenant, with respect to your wing commander and his involvement with the medical people on base, have you witnessed any interaction between them, any action by the wing commander to try and address this issue with the medical people?

Lt. ROVET. He has shown significant interest, sir, in the health and welfare of his wing, as should be. A man of amazing core values and personal fortitude and strength. Just wish you could clone him. But he has—yes he has been very involved with my medical group commander and my squadron commander, who both are very

wonderful people also who I know have been putting in long nights, sleepless nights, over this program.

And just like to make a statement concerning our medical program at Dover. Originally, we had some bugs to work out with the adverse reaction reporting. There was—it just came so fast and furious, the reactions and what not. And we may have not handled things appropriately in the beginning. And as humans, we learn our lesson. But I do believe that under the leadership of Colonel Greider and Colonel Buck and Colonel Luna and down through the AMDS squadron where I work, including public health, we have a pretty good system now. And we have identified some of the short falls, and we will be aggressively, I can assure you, pursuing a cogent reporting that can be very valuable to not only our service men but to our country at large.

Mr. TIERNEY. Would you be a little more specific about what has changed with this vaccine program on your base. Originally there was a high threshold. What I mean by high threshold, when patients were to come in, they would be—there was that reticence in the beginning that I was talking about. The threshold, a doctor would be viewed as a filter. The doctor would say, if they would go ahead and check the box up in the right-hand corner—I forget the box on the VAERS form—that would be a provider saying, my gosh, you know, that is a bona fide reaction; I kind of believe this. So that would lend validity to the report.

To date, no provider has ever signed a VAERS form or checked the box off.

OK.

Mr. TIERNEY. That hasn't changed? That continues to be the case?

Lt. ROVET. That continues, but what we have now is lowering of the threshold when more people come forward. And I think, and I am not an epidemiologist, sir, but I think that will statistically even out the more reports that we get coming forward if we can start—the researchers at Brooks Air Force Base, at the FDA, at Walter Reed—that's a problem in itself, it is so spread out. Bureaucracies have a tendency to do that, I guess.

Mr. TIERNEY. So I hear.

Lt. ROVET. But what I think what we are going to do is see it work its way out in the end. The more data we get, we'll let the numbers just work themselves out. So it is changing. It is a lower threshold, and the medical group at Dover now is right on it.

Mr. TIERNEY. Well, Captain Piel, do you think somebody in your circumstance would be treated better today than you were treated?

Capt. PIEL. I definitely hope so, sir. I would suspect that they would be treated better after everything that has happened. Things have changed.

Mr. TIERNEY. Do you think they have made some positive adjustments as a result of your situation and others.

Capt. PIEL. I think that they are working on it.

Mr. TIERNEY. With room to go?

Capt. PIEL. It is a very difficult problem, and it is not something you can just solve or correct overnight.

Mr. TIERNEY. What might you suggest that could be done on your base that would make it easier for somebody in your circumstance?

Going back to the beginning of your circumstance, what would have made your experience——

Capt. PIEL. Well, I think if my case had been forwarded to Walter Reed sooner, that definitely would have helped because Dover doesn't have a lot of doctors. We have a pretty small clinic. It is not necessarily one of your large medical centers where they can deal with all different types of problems. There aren't specialists that you can go see. You get farmed out to everyone else.

So if I had been forwarded to the immunology clinics at Walter Reed sooner, that would have helped. You know, in the process, I kept getting referrals to ear-nose-throat doctors, and they can take care of my ear, but they can't take a look at my whole body.

Mr. TIERNEY. OK. Thank you. Sergeant Soska, do you have a feeling that there is a difference at your base also between the way the medical professionals treated individuals and the way that the chain of command did?

Mr. TIERNEY. Mr. Tierney, I can tell you from a personal standpoint that and what I have went through for the last year and the acceptance by both the division surgeons, both the outgoing and the incoming, have been, they have been there for me. In talking with Lieutenant Colonel Carrigan, who is our new division surgeon, 3 hours on 2 separate days, took an active interest in my situation after speaking out before the Anthrax-Persian Gulf Illness Outreach program meeting we had there.

They took an active role in it. I would like to comment on similar problems she had where it took so long to get to the right areas. It was here, go here, and there was always a long wait in between.

Yes, the doctors were trying. They didn't have the answers. But it is just the way the system is set up, sir.

I feel that in my situation and in talking with Lieutenant Colonel Carrigan, who apparently was a member of that hundred-doctor meeting in Fort Detrick, my indication I got after talking to him was that I think they realized there is a situation here and they are trying to make an effort to just see how big it is.

I can't say anything negative on that aspect about them. I think there is genuine concern within the ranks and the leaders themselves. They are seeing this happening more and more. And just like myself—and I may add, the comments I make here are mine, I am just saying what is happening to me and what I have witnessed. And that is the impression I have been given, sir.

Mr. TIERNEY. Thank you. Lieutenant Colonel Jensen, you have some particular problems in your division, I assume, because of the Guard, those units having a different access to medical attention than others do. Do you want to talk a little bit about that?

Col. JENSEN. If I understand you correctly, sir, our access to medical care basically the shot in the Guard—my unit has not received the shot yet. We are not due to receive it until May 2000; however, due to operational commitments, I believe we have approximately 100 individuals who have received the shot, or the series.

In the Guard as in the Reserves, you are placed on active duty for the shot. And that is for, my understand is I am told, a medical requirement so if something happens to you, you can come back and provide you. It also has the opportunity, obviously, if you are

on an active duty status, then you can be given a direct order should you choose to refuse the vaccine.

For instance, if somebody were to have a reaction the next day, if they were a traditional Guardsman or civil service employee such as myself, primarily I would have to go and seek medical care through the civilian community and/or come back to the military community and attempt to file what they call a line-of-duty statement in which—and that would only be filed if the, as I understand it, if the medical community deemed that the vaccine was causal to the condition.

The line-of-duty statement is filed if you have a loss of duty. For instance, a hypothetical situation, or I will give you a real case situation, if I may.

We have an individual that was in that series shot and he was on active duty, placed on orders, I believe, or on a Reserve active duty status, RUTA as they call it, and the next day he took 24 hours of sick leave. He is a fireman and he is on a 24-hour schedule out of his own sick-leave time due to flu-like symptoms that he placed on his sick leave form as caused by the anthrax vaccine.

He did not seek medical attention. OK? And as such, basically he ended up taking 24 hours of sick leave. An important note here, I believe, is that even if he followed the line of duty status on that, the way I am told by my finance officer is he would not be reimbursed for the sick-leave time. He is only reimbursed if he physically or she physically has a loss of pay.

So if you have sick leave, you haven't lost any pay.

Does that answer your question, sir?

Mr. TIERNEY. Yes. Captain Richter, does—secondarily to obviously the medical implications of all this, the individuals, it is disturbing to hear about the loss of trust that you talk about in the—I'd like to hear your ideas of how that trust might be restored in this instance.

Capt. RICHTER. Well, at this point I don't know. That is a hard question to answer. I don't know if the trust can be restored. The obvious thing would be at least, first of all, come out and say there is a problem. Acknowledgement would be 99 percent of it. Continuous denial that these symptoms are from some other cause is not helping matters. Like I mentioned, Colonel Greider, our wing commander, went and stopped all the vaccinations for a period of time until he could address the situation, find out what was going on, try to allay everybody's fears, and get it rolling again.

I don't know what the outcome of that—again, I am just a reservist. So I am there only part time, unlike my counterparts who are there all the time—active duty. But I got a feeling he was called down to Washington and called on the carpet because shortly thereafter Lieutenant General Roadman came up and said: Hey, take the vaccine. There is no problem with it. The percentages of people having problems is minuscule. These are your marching orders.

So I think just an admission that well, maybe there are more than just a few people having these problems would help. I mean, that would start the ball rolling to be sure.

Mr. TIERNEY. Thank you. I just want to echo the chairman's words that all of you show great courage coming forward here today. And patriotism doesn't always take place on the battlefield.

I want to thank you for your courage.

Mr. SHAYS. Congresswoman Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. And I too want to thank you for your personal courage in coming forward and all the things that led up to today, and also express my concern regardless of what one thinks about the vaccine that it takes so much courage just to speak out on these issues.

I have a number of questions. I wanted, Captain Piel, to note that in testimony that I don't believe that you read, that you were told by some doctors things, comments such as, you're depressed; maybe you just want to have babies; called a malingerer; perhaps you need counseling.

These clearly are very demeaning kinds of things and would contribute to your feeling of not being believed for sure, but you also say that you still don't have—even now, I still don't have a waiver. Can you tell me about waivers? How does one get one? What do you mean by a waiver?

Capt. PIEL. Well, a waiver, what I mean is to get a waiver from further anthrax immunizations.

Ms. SCHAKOWSKY. And how does that happen?

Capt. PIEL. I have no idea exactly the process for that.

Ms. SCHAKOWSKY. There is such a thing though? Can anyone answer that?

Capt. PIEL. Well, that is just under the guise that there are waivers for everything. [Laughter.]

Ms. SCHAKOWSKY. Oh, OK. Can any of you testify to that?

Capt. RICHTER. I can comment on that. I am on a medical waiver right now. It is just a temporary one, but I am on a temporary medical waiver, and I do not have to take the next injection until they figure out the results of my first visit. I am now scheduled to see a rheumatoid arthritic doctor at Bethesda next month. So I have a waiver that will take me through August, until I go see him and he discusses what my problem is.

Ms. SCHAKOWSKY. And while on waiver, are you allowed to carry out your other duties. For example, would Captain Piel be able to fly?

Lt. ROVET. Ma'am, I really think I could answer this one cause it is in my department where we work.

Ms. SCHAKOWSKY. Take your time.

Lt. ROVET. Excuse me, Captain Richter, I didn't mean——

Capt. RICHTER. Go for it.

Lt. ROVET. What a waiver actually is, is more than just a verbal granting of like a person has a doctor's note that says you can't fly. It has to be sent up headquarters and has to be evaluated and blessed and filter back down.

What they are looking at right now, and this is again my perspective. It is not policy, but I think this is going to be a logistical problem and a personnel problem that is going to crop up here shortly. So we need to be pro-active on this issue.

If individuals are seen and evaluated, and again the key word is evaluated—who is going to be the actual medical body that is going

to evaluate and say this individual cannot receive the vaccine? What they do is they put on the profile. At that point, it is an official profile. And then they get given a medical board.

What they are looking at doing is giving these people a C code, waiver C code, which means they can continue out their duties and fly, but they won't be able to go into Southwest Asia or Korea, areas where high threat of bio-attack or chemical attack. That is going to present its own nightmares.

Just a scenario, if a pilot's air crew member is in Mildenhall, England, and that's OK. He can fly there. Then they get a tasking to say go down range to Southwest Asia—there is going to have to be a centralized tracking system of which pilots are on C codes. So they will have to bump that air crew member, put on somebody that can fly down there, who has the anthrax vaccine, to complete the mission.

This is going to present some problems.

Ms. SCHAKOWSKY. But I did want to establish that there is some kind of individual waiver policy that could exempt certain people currently.

Lt. ROVET. Not right now in the Air Force. And, again, that is just my opinion. But we are still looking for answers on that, ma'am.

Ms. SCHAKOWSKY. OK. We'll try and establish that.

I wanted, Sergeant Soska, to ask you, you testified the procedures are not being followed as spelled out in AVIP documents. What did you mean?

Sgt. SOSKA. Well, ma'am, in my written testimony, on January 27th I was given an MGC meningococcal, I believe is the name of it. This was after—I was graciously overlooked; my chain of command knew I was having problems after the first three shots that I received. When I went down there for that, I explained to the NCOIC in charge that hey, I am under B–12 replacement shots. For some reason my system will not retain B–12.

And she concluded that, yes, it would be a bad time to do it. But I did have to get what I call the MGC or meningococcal shot.

Up to this point I was having problems all along in my testimony, but after I got that vaccination, on the 29th, went to PT, I did my normal profile PT thing, went home from work, had two cups of coffee, was coming back into work, and started feeling rough. After formation, I managed to get to the troop medical clinic, which is right next door.

I remember being escorted back to the treatment room, and then I don't remember much after that cause I was out of it. I totally locked up. I didn't know what happened. I was out.

And, my understanding, I was reading some of the AVIP documents and what else, and I don't fault the doctors. I think they are outstanding doctors that have been taking care of me. I just think there is a lot of areas that, you know, we're not, we don't do all the time or we don't practice all the time. And some of the stuff is falling through the cracks.

But it is in my medical records, but how come it wasn't reported. It wasn't until later that I spoke up in the Persian Gulf Illness meetings that, you know, the attention—my attention got to the division surgeon, and they started really looking into it.

So, forgive me if I ramble, I have problems staying on track some times.

That's what I say, it's really not being reported like it should. Others that have been with me, have been to Southwest Asia and that have came back, are having similar problems. And I reiterate, they are afraid to say something.

But, you know, the problem, the problem is there.

Ms. SCHAKOWSKY. Captain Richter, you said in your testimony, "The threat of being exposed to—the doctor went on to say that the threat of being exposed to anthrax while in deployment outweighed the possible negative reactions that some military personnel might have to the vaccination" and that it was not a matter of if but when some of our troops would come in contact with it.

So I want to get to the issue of threat versus the risk of the vaccine and wonder what your feeling is that if the threat is so great and if 99 percent of those who inhale anthrax spores would die, which seems to be the science there, then at what level do you feel the risk is acceptable? I mean, how serious—if the threat is so great, at what point should the Department of Defense say, well, this is what we have to do?

Capt. RICHTER. I don't know if I am qualified to answer that really. For me, I can only speak for myself, I go in, I drill once a month, I maybe take a trip down to the Middle East. I have another job. I am an airline pilot out in the commercial sector as well.

My health is my life, and the odds that I am going to go down range to the Middle East somewhere and get exposed to anthrax, I think, is probably pretty minute. If I was called on active duty, it would be a different story, but, having said that, my—at this point I just can't afford to gamble because I have to feed myself with mostly my outside endeavors, my outside job.

I think what he was trying to really lay out was the policy of the DOD. I don't think that was really his opinion. When I was discussing this with him, we were kind of in a continuous tail chase. I kept telling him, well, if I feel this bad and I pretty darn sure it came from the anthrax, then what is the point in me taking another one if ultimately I am not going to be any good to the military if I am not functional.

And that is when he was saying, you know, that a few people may have a negative reaction; however, overall, we need to protect the troops en masse, and that risk is worth taking, to vaccinate everybody with the expense of a few.

Ms. SCHAKOWSKY. Well, maybe part of the answer then is in my next question to Lieutenant Colonel, maybe you can answer it. You said in your testimony, you would welcome a safe and effective vaccine. I don't know if we are all in agreement here that that is an important goal. I would think that we are, that there is a real threat.

I had a wonderful briefing yesterday that convinced me that there is enough reason to think that we need to find a vaccine.

Are you saying that we need to do more to develop a safe vaccine?

Col. JENSEN. Based upon what I have heard, what people have told me, the anecdotal evidence, I think there is a tremendous concern out there that the safety of the vaccine may not entirely be

what it was made out to be. You talk about what is the risk. We are in a timeframe of dwindling budgets, where we are constantly told that we are going to have to do more with less.

If you take Dover, for example, if the numbers, if I remember correctly in testimony here today, you have about 1,000 people that were vaccinated there. And out of those folks, you have got six, is my understanding, that are still permanently denef, some over 6 months after taking the vaccine. The cause is still unknown.

You have got 30 people that are potentially being worked up at Walter Reed. You heard testimony that related to the potentially three times those folks that are out there are having similar reactions but are not reporting them for a variety of reasons.

That creates a far greater concern too that whether it is caused by the anthrax vaccine or not, I have individuals out there that are not being provided proper medical treatment, and therefore we may have a false sense of security as their ability to perform their job, thinking that they are 100 percent capable when, in fact, they are not.

You heard the numbers cited for those that are leaving the Reserve squadron, let alone. So you may have, you know, if you take the threefold, you may have upwards of 100 people or 10 to 12 to potentially 15 percent of your combat force which may not be ready to enter or perform the mission that we are assuming they are capable of.

And you have not even entered a theater yet before you can be exposed to the vaccine—excuse me, exposed to the threat of the weapon.

Ms. SCHAKOWSKY. So on the question of readiness, we need to be concerned about the effect of the vaccine itself?

Col. JENSEN. Yes, ma'am, I think it is the classic risk-management or risk-analysis that has been preached by the Army program that was developed and the Air Force has adopted, is truly look at what are the cause and effects across the board in that fashion.

Ms. SCHAKOWSKY. Thank you very much.

Mr. SHAYS. We have a system where, in the United States, as a force protection we require, at least in phase one, for our military personnel to take the anthrax vaccine for those who are in areas that may require them to be protected. And then there is a question of whether we go to phase two, which would be the military personnel who aren't directly anticipated to go into areas where they might even be exposed.

We have another country, Great Britain, that has decided to use the vaccine and made it voluntary. And we have the French who looked at the vaccine and decided that this would be a mistake, at least so far.

And, I am struck by a lot of feelings as I listen to you all make your testimony, and I heard the excellent questions and responses to those questions, the questions asked by my colleagues.

And I am also reacting to the varied circumstances each of you have. Captain Piel, you are in the active duty. You aren't a reservist; you are not in the National Guard; you don't work for a commercial airline. But you are a pilot.

Capt. PIEL. That is correct.

Mr. SHAYS. And my understanding is you fly C–5's?

Capt. PIEL. That is also correct.

Mr. SHAYS. Yes. And someday, when you are out of the military, there is the potential that you might continue to fly. Is that also a possibility?

Capt. PIEL. Sir, I was hoping to fly the rest of my life.

Mr. SHAYS. Yes. Sometimes, not often, but sometimes we have had witnesses come before us, say with the Gulf war illnesses, and you heard very important stories. But you kind of doubted—sometimes I am just saying to myself, I didn't, I wasn't fully convinced of every witness that came before us when it dealt with the Gulf war illness.

So I believed the vast majority of them. And that is why this committee moved forward.

But there is not a scintilla of doubt in my mind about the testimony I have heard from you and others. You want to fly. So you don't want to be sick, and yet your illness was at a point where you must have made a determination that you might endanger the command of your plane. So you stepped forward.

There are others who might be on the margin, who, if they could have the faith that they would be treated with respect, would step forward. And if they doubted—even if that doubt isn't, if it's a doubt that they believe, even if it is not justified, the doubt would lead them not to do what action they should take.

You did the right thing. You weren't well and you came forward. And now you are paying for it big-time.

Others saw that, and they are going to say, I am going to do whatever I can to avoid coming forward.

So first and foremost, I just want to say, I really accept the fact that you are dealing with some heart-wrenching concerns.

Captain Richter, I will say to you, if I was a commercial pilot, besides being a Reserve pilot, there is no doubt in my mind. I wouldn't take the chance. And that doesn't pre-judge how ultimately this committee is going to decide.

We have had three hearings. This is the fourth now. And we don't know ultimately what we are going to recommend, but we are going to be recommending some course action of the committee itself.

But I have to tell you, I would do the same thing you are doing. I would not jeopardize for a minute that source of income that provides you the opportunity to support your family.

And so it raises a lot of questions for this committee. Do we suggest that this program be totally discontinued? We have one source provider. We have old technology. Another is, do we suggest to be voluntary? Another is, do we suggest that if you are going to do phase one, you do it for the people who are clearly going to be in the theater, but others you are not going to phase two.

We are wondering why it is all right for the military to deploy you in an area of concern, in a theater of concern, after beginning the first shot—you can now be deployed. So the military is given the option that they can send you into harm's way, but you don't have the ability to say "no" to the shot.

You are not given that other option.

It would be interesting to know, and we will ask our next panel, are you given the option since the military says you need six shots that you should not be deployed until you get six shots.

Another question that is raised is, what kind—how are they treating people who, military personnel who have had the first shot and have reacted negatively to it. Shouldn't that give you additional rights to say "no."

So a lot of questions are being raised. And it is also a fact that you have been very respectful of your command. All of you have. And the problem we have is knowing how far we push you without putting you in a different kind of harm's way. Because no one could listen to anything you have testified and say you haven't—in a sense, we are a command too. And we asked you to be here and you accepted our request.

And, but you all have been very respectful.

It fascinates me, Mr. Rovet, that you have, you are not, you a medical personnel. You are in that area. And so you are stepping forward. Have you been asked to take this vaccine?

Lt. ROVET. No, sir.

Mr. SHAYS. So you are stepping forward because of what you know, and if you didn't step forward and things happened in the future, you would have to live with that the rest of your life.

Lt. ROVET. Yes, sir.

Mr. SHAYS. So, we appreciate you stepping forward for that reason, among others.

So we have someone in active duty; we have someone who has a medical background and has seen how it is operating and it's not a pretty story. Sergeant, we appreciate your testimony as well.

We have two pilots. What fascinates me is, in the area where I have the most conviction that if I spent a good chunk of my life learning to become a pilot, I would do nothing to jeopardize my not continuing to fly. And yet we have in the National Guard and Reserves, we have a plethora of talented, capable people who are saying, I am not going to take this vaccine; I am leaving.

And I have to believe that leaving—that you enjoy, Captain Richter, and I will just—tell me the difference: You are serving your country, that is clear, but do you meet all your flying—tell me the difference of being in the Reserve and being a commercial pilot.

Capt. RICHTER. Well, first and foremost, it isn't as much fun.

Mr. SHAYS. Which way?

Capt. RICHTER. Being in a military pilot is probably more fun than being a commercial pilot. I guess the most gut-wrenching thing I have had to face, that while I saw myself continuing to serve in the next 8 years, I am being forced into a position where I take this shot and perhaps my condition will get worse, perhaps it won't. I don't know.

But it is that fear of the unknown that will not only affect my military flying, but it will also affect my commercial flying. Everybody needs to be healthy to do their job. We, as pilots, need to be 100 percent healthy to do our jobs. And if there is any question or any doubt about what something is going to do to you, at least——

Mr. SHAYS. What do you fly as a commercial pilot?

Capt. RICHTER. I am a prop pilot out of Dulles. I fly for Atlantic Coast Airlines.

Mr. SHAYS. And in the military you fly?

Capt. RICHTER. C–5 as well.

Mr. SHAYS. Lieutenant Colonel Jensen, what do you fly?

Col. JENSEN. I fly F–16's, sir. I am an instructor-pilot with nearly 2,000 hours in the F–16.

Mr. SHAYS. OK. The bottom line to both of your testimonies is we are losing a lot of good pilots. Is that not correct?

Col. JENSEN. That's correct.

Capt. RICHTER. That's affirmative. A lot of them.

Mr. SHAYS. Yes. OK.

Capt. RICHTER. They just can't afford to take the gamble. And most of them can afford to give this job up, as much as they don't want to. Because it is, like I as I said, it's a good, fun thing to do to be still serving your country.

Mr. SHAYS. I am going to have—the counsel is going to ask a question that Mr. Souder wanted to ask, but beforehand I just, I am going to do two things. One, I read again Mr. Jensen—Colonel Jensen—what you read. This is a memorandum of decision, and it deals with the authority under Public Act 85–804 to include an indemnification clause in the contract.

And I am just going to read it again, and I am just going to think of what people think who are being asked to take this shot: The obligation assumed by MBPI under this contract involves unusual hazardous risks associated with the potential for adverse reactions in some recipients and the possibility that the desired immunological effect will not be obtained by all recipients.

Which, that in a sense means, the whole clause means it may hurt you and harm you, and in the end, it may not even work. And the company is being indemnified.

I understand why, but I can understand the concern when you read that.

Now, I will end my part by just asking if any of you would like to make a closing statement, because really you answered the questions. I was able to get more into a monolog because you really answered the questions of my colleagues.

Would any of you like to make a closing comment?

Captain Piel.

Capt. PIEL. Yes, sir. There is one thing I would like to say. I understand that we can make decisions based on acceptable risks; however, I feel that we need to know exactly what those risks are. And the VAERS system doesn't seem to be adequately providing information.

And that is all I wanted to say.

Mr. SHAYS. Thank you. Lieutenant.

Lt. ROVET. Mr. Chairman, I would like to echo that. Informed consent is based upon having information up front. I know there may be some legalities that military may not need informed consent. I am not quite aware of that. But I think if this comes to light that the reaction rates are much higher, and now the rhetoric is changing to the risk outweighs—I mean the benefit outweighs the risk, we are opening up a moral pandora's box that is worse than any dusting with anthrax vaccine.

Mr. SHAYS. OK. Sergeant Soska.

Sgt. SOSKA. Congressman Shays, on a personal note. My son told me about 4 or 5 months ago—excuse me if I get a little emotional on this one—he says, dad, mom told us to pray about you. And I asked him, why. He says, because she sees you getting sick and it worries her. That hit home, sir.

It is not just about me. This is affecting a lot of people that are having problems. And I encourage all soldiers in all branches, and as a mentor, my command sergeant major said to me, sergeant, don't put yourself in a position where things can be misconstrued. They are having problems, and they are not getting the help they need, they need to bring it to the chain of command. The only thing you can do is advise them what to do, nothing more, nothing less.

And I thank him for that.

That is all I have to say, sir.

Mr. SHAYS. Thank you, Sergeant. Captain Richter.

Capt. RICHTER. I think I have said enough, sir. I have nothing else to add.

Mr. SHAYS. Thank you. You have been very helpful.

Colonel Jensen.

Col. JENSEN. Sir, if I may take a moment to address the question that was posed about risk and benefit?

Mr. SHAYS. OK.

Col. JENSEN. I think one of the things when you get into that risk versus benefit analysis is a true analysis of the efficacy of the vaccine. And for that, I would offer this as an area to explore.

On the DOD anthrax web page, they talk about the vaccine efficacy, excuse me, has been tested against numerous anthrax strains in animal models. They talk about the guinea pig and the mice are poor animal models for anthrax vaccine testing. However, they consider the rabbit to be a more appropriate one, and the monkeys are considered the best. Yet I see nothing in documentation that equates that to the studies that say, this is why these are better models.

For example, yet mice are labeled to be poor, numerous guinea pigs and mices have been tested and their reaction rates or survival rates can range anywhere from 10 to 90 percent. The rabbits I am unaware of what the rates are, but I am told they are extremely good survival rates.

The few monkeys that have been tested have a very high rate. Is the reason that the monkey and the rabbit are being viewed as the more appropriate models because they appear to survive the vaccine better? Or is there an actual study to support that?

And on an interesting side note, the guinea pigs and the mice that are considered poor animal models for this exposure against inhalation anthrax, the mice have been used extensively by the Air Force with regards to the Air Force Office of Scientific Research, the folks that are doing the inhalation studies right now, and have been for the last 4 to 5 years out of the University of Arizona under Air Force contract.

They have been using mice extensively to examine the respiratory effects that inhalation of jet fuel, in particular JP–8, have. And they use that as the model to compare to human studies. Mice are also used extensively, I am told, in cancer research because of the ability to—or their life expectancy is so short they can see that.

Guinea pigs, they state again, are poor animal models, and yet my understanding is the guinea pig is used pretty much exclusively to test the potency or the efficacy of the vaccine before the lot is released.

So, you know, I kind of sit here and beg the question. OK, in some cases, why is it good here, why is it not good there? And just looking for the published studies that indicate, because I have also seen other folks or heard statements by folks out of the medical field that question truly what is the, you know, have the models been actually made.

Mr. SHAYS. I'm beginning to think I should hire you as one of our staff members. [Laughter.]

Col. JENSEN. Do you have F–16's that I can fly here, sir. [Laughter.]

Mr. SHAYS. OK. Well, I am just going to say one last point, and that is that there is something we can do before our report, and that is that we can encourage the military to make sure, in their chain of command, they encourage proper reporting and don't discourage people to step forward.

We can do that.

And I believe that would be something that we could have some positive result on. And that would be something we can do now.

Thank you very much. Been wonderful witnesses. Appreciate you being here.

We will get to the next panel.

Our next panel is comprised of Kwai Chan, Director of Special Studies and Evaluation Group, National Security and International Affairs Division, U.S. General Accounting Office, accompanied by Dr. Sushil K. Sharma, Assistant Director from the same division.

Our second testimony will be from Major General Roger Claypool, Deputy Assistant Secretary for Health Operation Policy, U.S. Department of Defense, accompanied by Rear Admiral Michael Cowan, Deputy Director for Medical Readiness, Joint Staff, U.S. Department of Defense; Colonel Frederick Gerber, Director of Health Care Operations, Office of the Army Surgeon General, and Colonel Renata Engler, chief, Allergy and Immunology Service, Walter Reed Army Medical Center.

And our third testimony is from Susan Ellenberg, Director of the Division of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, Food and Drug Administration, commonly referred to as FDA.

I want to make sure we have enough seats there and that everyone is comfortable. There will be one or two others who——

[Pause.]

Mr. SHAYS. Everybody I called, are they represented up here. Is there anyone who is not sitting at the front desk.

OK. Whoever isn't at the front desk but will potentially be asked to come forward, I will be asking them to step forward.

Do we have enough room there?

Yes. OK.

Are we OK, Jason?

OK. Is there anyone who is up who was not called but will be potential witnesses so we have their name to give——

OK. Could you state your name please?

Dr. BRAUN. Dr. Miles Braun.

Mr. SHAYS. Doctor, I am going to have you, just so the recorder can get it—do you have a card? Did you give your card to the reporter?

Dr. BRAUN. Yes.

Mr. SHAYS. Just state your name again, sir.

Dr. BRAUN. Miles Braun.

Mr. SHAYS. Dr. Miles Braun, thank you very much.

If I could, I would invite you all to stand.

If you would raise your right arms, please.

[Witnesses sworn.]

Mr. SHAYS. Thank you.

I am going to state one bit of prejudice first and then invite the testimony. And that is, I think the thing that causes me the greatest concern and can make you a bit annoyed is the thought that our soldiers and other military personnel, our pilots, our airmen, and so on, our Navy personnel, Marines, would feel in any way intimidated from stepping forward if they thought they had an adverse effect.

And I am just going to go under the assumption that that would trouble you as much, any of those of you—and that from a military standpoint that this will be something that you will make clear would not be treated well if you thought that any in the chain of command were a part of that, and that just as you might be, challenge someone who think they have an adverse effect and you think they have not done it in a proper way, you would be just, if not harder on those who would make someone feel intimidated to step forward.

I do welcome this panel. It is an excellent panel. And we will start with you, Mr. Chan, and we will then go to you, Major General Claypool, and we will then go to you, Susan Ellenberg.

Is it Doctor, am I? I am sorry.

Usually my staff corrects me. And I just have this feeling you must be a doctor. So you can give me that check.

OK. Let's start.

Thank you, Mr. Chan.

STATEMENTS OF KWAI-CHEUNG CHAN, DIRECTOR, SPECIAL STUDIES AND EVALUATION GROUP, NATONAL SECURITY AND INTERNATIONAL AFFAIRS DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY SUSHIL K. SHARMA, ASSISTANT DIRECTOR, SPECIAL STUDIES AND EVALUATION GROUP, NATIONAL SECURITY AND INTERNATIONAL AFFAIRS DIVISION, U.S. GENERAL ACCOUNTING OFFICE; MAJOR GENERAL ROBERT CLAYPOOL, DEPUTY ASSISTANT SECRETARY FOR HEALTH OPERATIONS POLICY, U.S. DEPARTMENT OF DEFENSE, ACCOMPANIED BY REAR ADMIRAL MICHAEL COWAN, DEPUTY DIRECTOR FOR MEDICAL READINESS, JOINT STAFF, U.S. DEPARTMENT OF DEFENSE; COLONEL FREDERICK GERBER, DIRECTOR, HEALTH CARE OPERATIONS, OFFICE OF THE ARMY SURGEON GENERAL, U.S. DEPARTMENT OF DEFENSE; COLONEL RENATA ENGLER, CHIEF, ALLERGY-IMMUNOLOGY SERVICE, WALTER REED ARMY MEDICAL HOSPITAL; AND SUSAN ELLENBERG, DIRECTOR, DIVISION OF BIOSTATISTICS AND EPIDEMIOLOGY, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY DR. MILES BRAUN

Mr. CHAN. Thank you, Mr. Chairman.

Mr. Chairman and members of the subcommittee, it is indeed my pleasure to be here today to share the results of our work on the anthrax vaccine. And may I also introduce my colleague, Dr. Sharma, and my staff in the back of me, Dr. Howard DeShong, who helped me with this work.

As you know, many questions have been raised about the Department of Defense anthrax immunology program. We have previously reported to you a number of concerns regarding the safety and efficacy of the vaccine. Today, I will present our findings on four issues.

First, the extent to which data support the need for six initial shots and annual booster for the anthrax vaccine. Second, the relationship of—the relative merits and weaknesses of passive surveillance system for monitoring adverse events. Third, available data on differences on adverse reaction rates between men and women. Finally, the disadvantages of the current vaccine and the status of Federal efforts to develop an improved anthrax vaccine.

With regard to the first question, what is the support for the current regimen of six-dose schedule and an annual booster shot? We found that the current six-dose schedule was arbitrarily determined. No studies have been done to determine the optimum number of shots required. And although annual boosters are required, the need for this frequency and amount of the booster dose have not been evaluated.

Second, with regards to what are the relative merits and weaknesses of passive surveillance systems? That is the VAERS system that you have heard about, which DOD used to determine the rate of adverse events. We found that this system has several advantages as well as disadvantages.

The advantages: It alerts FDA and CDC to previously unreported or unexpected increases in reported adverse events. It is also a rel-

atively affordable way to supplement the data collected on vaccines before they are licensed.

However, there are several disadvantages. Studies show that adverse events are often under-reported in a passive surveillance system. A former FDA Commissioner acknowledged that under-reporting of adverse events in such systems and cited one study showing that, ''Only about 1 percent of serious events,'' are attributable to drug reaction reported to FDA. That means 99 percent are not reported.

Also, outcomes with delayed onset after vaccination are outcomes not generally recognized to be associated with vaccination are often under-reported.

There is no mechanism within VAERS for a 1-, 3-, or 10-year followup to evaluate vaccine reactions that have a long latency period.

The limitations of VAERS suggest it is not a valid source for assessing the rate of adverse events.

With regards to the third question, on gender differences, we identify three DOD efforts which examine gender difference with regards to adverse events. Data from these efforts show that women reported twice the rate of adverse reaction than men for both local, for example swelling, and systemic reactions, for example malaise and chills. And we observed some reactions—these reaction rates to increase with each successive shot.

In addition, a high proportion of women than men reported making an outpatient medical visit after a vaccination, and more than twice the percentage of women reported that they missed one or more duty shifts after their vaccinations than men.

Finally, with regards to your fourth question, we found that the current vaccine has several disadvantages. It is an impure mixture of bacterial products using outdated technology. The amount of protective antigen in the vaccine cannot be precisely measured, and it varies from lot to lot as you produce them.

There is some evidence that the current anthrax vaccine may have diminished efficacy against certain virile strains of anthrax. Also, the requirement for a six-dose schedule and annual booster shots complicates the logistics of inoculating all of DOD's troops and increases the cost of the vaccine program.

Knowledge of anthrax infection in studies of experimental anthrax vaccine indicate that a second-generation vaccine with a more precise amount of protective antigen could be developed and that fewer doses of the vaccine could be required.

In 1995, the U.S. Army Medical Research Institute of Infectious Diseases developed a second-generation recombinant vaccine against anthrax. The vaccine was tested on animals, but clinical trials were not conducted in humans.

DOD currently considers such a vaccine an unfunded requirement. The Department of Health and Human Services has allocated funds to develop a second-generation recombinant vaccine because of a perceived bio-terrorism concern.

In developing this second-generation recombinant anthrax vaccine, researchers believe they will need to address the additional problem of whether deliberately engineered or natural strains of anthrax can overcome the protective immunity of such a vaccine.

Mr. Chairman, this concludes my statement.

Thank you.

[The prepared statement of Mr. Chan follows:]

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United States General Accounting Office

Testimony

Before the Subcommittee on National Security, Veterans' Affairs, and International Relations, Committee on Government Reform, House of Representatives

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MEDICAL READINESS Issues Concerning the Anthrax Vaccine

Statement of Kwai-Cheung Chan, Director Special Studies and Evaluations, National Security and International Affairs Division

GAO/T-NSIAD-99-226

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to share the results of our work on the anthrax vaccine. As you know, questions have been raised about the Department of Defense's (DOD) anthrax immunization program because of concerns related to (1) the safety and efficacy of the vaccine and (2) problems found over the past few years by the Food and Drug Administration (FDA) during its inspection of the facility that was manufacturing the vaccine. We reported our findings on these issues to you in previous testimonies.[1]

In December 1997, the Secretary of Defense announced that all U.S. forces would be inoculated against the potential use of anthrax on the battlefield. Although a version of the anthrax vaccine was shown to be effective against cutaneous exposure, the vaccine has not been tested against inhalation anthrax in humans. DOD has recognized that some of the concerns about using the current vaccine might be mitigated in the future through actions such as testing and research and adjustments to the program based on new data.

As requested, we will discuss (1) the extent to which data support the need for six initial shots and an annual booster of the anthrax vaccine, (2) the relative merits and weaknesses of a passive surveillance system in determining adverse events,[2] (3) the available data on differences in adverse reaction rates between men and women receiving the anthrax vaccine, and (4) the disadvantages of the current vaccine and the status of federal efforts to develop an improved anthrax vaccine.

Results in Brief

No studies have been done to determine the optimum number of

doses of

the anthrax vaccine. A study done during the early 1950s showed that animals could be protected against cutaneous anthrax using a three-dose schedule. However, the number of doses was increased to six when three people who had received three doses of the vaccine were infected after exposure to anthrax. In a study of the vaccine's human efficacy published

1 Medical Readiness: Safety and Efficacy of the Anthrax Vaccine (GAO/T-NSIAD-99-148, Apr. 29, 1999) and Contract Management : Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer (GAO/T-NSIAD-99-214, June 30, 1999).

2 Clinical events reported to a passive surveillance system are usually termed adverse events rather than adverse reactions because causally-related events to the vaccine is not usually possible.

in 1962, a six-dose schedule was used, and the researchers concluded that the vaccine provided protection against cutaneous exposure to anthrax. 3 In 1998, the current manufacturer of the vaccine submitted an FDA application (Investigational New Drug) to determine whether the number of shots in the initial schedule could be reduced from six to five. Although annual boosters are given, the need for this frequency and the amount of the booster dose has also not been evaluated.

DOD submits data on adverse events associated with the anthrax vaccine to the Vaccine Adverse Events Reporting System (VAERS).4 This system has several advantages. It alerts FDA/CDC to previously unreported or unexpected increases in reported adverse events. It is also a relatively affordable way to supplement the data collected on vaccines before they are licensed. However, it is a passive surveillance system, which means that FDA/CDC must rely on vaccine recipients or their health care providers to report any adverse events after receiving the vaccine; studies show that adverse events are reported significantly less than they would be in an active surveillance system. In an active system, which is generally more costly to administer, vaccine recipients are monitored to find out if

they had any adverse events after being inoculated.

In addition to reporting data to VAERS, DOD has conducted three efforts to actively collect data on adverse reactions after servicemembers received the anthrax vaccine. Data from these efforts show that women reported twice the rate of adverse reactions than men for both local (e.g., swelling) and systemic (e.g., malaise and chills) reactions. In addition, a higher proportion of women than men reported making an outpatient medical visit after a vaccination, and more than twice the percentage of women reported that they missed one or more duty shifts after their vaccinations than did men.

The anthrax vaccine has several disadvantages. The amount of protective antigen in the vaccine cannot be precisely measured, and it varies from lot to lot. Also, the requirement for a six-dose schedule and annual booster shots, rather than a smaller number of doses, complicates the logistics of inoculating all of DOD's troops and increases the cost of the vaccine program. Knowledge of anthrax infection and studies of experimental

3 P.S. Brachman et al., "Field evaluation of a human anthrax vaccine," American Journal of Public Health, vol. 52 (1962), pp. 632-645.

4 The system is an FDA/Centers for Disease Control and Prevention (CDC) system.

anthrax vaccines indicate that a second-generation vaccine with a more precise amount of protective antigen could be developed and that fewer doses of the vaccine would be required. However, a second-generation vaccine has not been fully tested, and the testing required for licensing alone would take about 3 years. FDA approval of the manufacturing of the vaccine would take longer. In 1995, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)[5] developed a second-generation recombinant vaccine (that is, a vaccine produced

through DNA extraction) against anthrax. The vaccine was tested on animals, but clinical trials were not conducted in humans. DOD currently considers such a vaccine an unfunded requirement. The Department of Health and Human Services recently funded several active research grants to develop a second-generation recombinant vaccine because of a perceived growing bioterrorism concern. In developing a new vaccine, researchers also believe they should consider the impact of new and engineered strains of anthrax.

Background

DOD currently plans to vaccinate all 2.4 million servicemembers against anthrax using the vaccine licensed in 1970 by the Division of Biologics Standards, National Institutes of Health (NIH). As of July 14, 1999, more than 300,000 servicemembers had received at least one dose of the vaccine. Initial immunization consists of three shots given at 0, 2, and 4 weeks followed by three additional shots given at 6, 12, and 18 months. Some studies have been done on the short-term effects of the licensed vaccine. We previously testified that the number of adverse reactions reported in these studies partly depended on whether an active or passive surveillance system was used to monitor adverse reactions.[6] Also, we reported that the long-term safety of the vaccine has not been investigated but that DOD is considering a study to examine long-term effects of the vaccine.

5 USAMRIID, an organization of the U.S. Army Medical Research and Materiel Command, conducts research to develop strategies, products, information, procedures, and training programs for medical defense against biological warfare threats and naturally occurring infectious diseases that require special containment. It is located at Fort Detrick, Maryland.

6 Medical Readiness (GAO/T-NSIAD-99-148, Apr. 29, 1999).

Data on the Need for

Six Shots Are Not Available

The original inoculation schedule of three doses was based on a regimen developed using animals in the early 1950s. However, three people (two in Fort Detrick and one in a private wool mill) who received three doses of the vaccine became infected after exposure to anthrax. The number of doses was then increased to six for the human efficacy study published in 1962. The study did not provide enough information to determine whether the vaccine was effective against inhalation anthrax. There were no studies done to determine the optimum number of doses of the vaccine. Also, according to DOD researchers, the choice of six doses was arbitrary. The license for the vaccine, which was granted to the Michigan Department of Public Health (MDPH),[7] calls for the six-dose schedule and annual boosters used in the human efficacy study, and DOD has followed this regimen. In September 1998, BioPort submitted to FDA an application (Investigational New Drug) to determine whether the number of shots in the initial schedule could be reduced from six to five.

In November 1971, the Division of Biologics Standards, NIH, noted an apparent increase in reports of adverse reactions after individuals received booster shots. The Division considered it advisable to reevaluate the need for annual boosters and possibly the amount of the booster dose. Although the record is unclear as to whether or not NIH requested a reevaluation, to date, no such reevaluation has been done.

The Relative Merits and Weaknesses of Passive Surveillance

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Systems in Determining Adverse Events

DOD submits data on adverse events associated with the anthrax vaccine to VAERS. VAERS is a passive surveillance system to alert FDA and CDC of adverse events that may be associated with licensed vaccines. Information is voluntarily reported to VAERS by health care providers, patients, or families, who are encouraged to report any adverse events after a person receives a vaccine.

VAERS has several advantages. It is a relatively affordable way to supplement data on short-term adverse events that are collected using active means during the clinical trials before a vaccine is licensed. Most important, however, VAERS serves as a signal for the detection of previously unreported adverse events and/or unexpected increases in

7 MDPH was granted the original license to produce the anthrax vaccine. In 1995, the facility changed its name to the Michigan Biologic Products Institute. In 1998, the facility was sold, and its name was changed to BioPort.

reported events. Prelicensing clinical trials are limited in detecting the range of adverse reactions because of the small samples, short durations, and the homogeneous population used as subjects. In addition, both the general public and doctors can report adverse events to the system, and the data is open to public scrutiny.

VAERS also has several disadvantages. Studies show that adverse events are often underreported in a passive surveillance system.8 A former FDA commissioner acknowledged the underreporting of adverse events in passive surveillance systems and cited one study showing that "only about 1 percent of serious events" attributable to drug reactions are reported to

FDA.[9] Reporting of adverse events appears to depend on several factors, such as the clinical seriousness of the event, the length of time between the shots and the event, and health care workers' awareness of and obligation to report particular adverse events. Also, outcomes with delayed onset after vaccination or outcomes not generally recognized to be associated with vaccination are often underreported. According to the National Vaccine Information Center, there is no mechanism within VAERS for a 1-, 3-, or 10-year follow-up to evaluate vaccine reactions that have a long latency period. According to CDC, the limitations of VAERS data suggest it is not a valid source for assessing the rate of adverse events.

In an active surveillance system, health care workers monitor people that have been vaccinated to find out if they have had adverse reactions. Such systems are generally used during clinical trials and are more costly to administer than passive systems because of the additional infrastructure and personnel required. However, such systems are sometimes used to obtain information when questions arise about the safety of a vaccine after licensing.

8 S. Rosenthal and R. Chen, "The Reporting Sensitivities of Two Passive Surveillance Systems for Vaccine Adverse Events," American Journal of Public Health, vol. 85 (1995), pp. 1706-1709; R.T. Chen et al., "The Vaccine Adverse Event Reporting System (VAERS)," Vaccine, vol. 12 (1994), pp. 542-550; and R.T. Chen, "Special Methodological Issues in Pharmacoepidemiology Studies of Vaccine Safety," Ed. B.L. Strom, Pharmacoepidemiology (Chicester: John Wiley and Sons, 1994).

9 D.A. Kessler, "Introducing MEDWatch: A New Approach to Reporting Medication and Devise Adverse Effects and Product Problems," Journal of the American Medical Association, vol. 269 (1993), pp. 2765-2768, and H.D. Scott, et al., "Rhode Island Physicians' Recognition and Reporting of Adverse Drug Reactions," Rhode Island Medical Journal, vol. 70 (1987), pp. 311-316.

Women Report More Adverse Reactions Than Men

In addition to DOD's reporting of adverse events to VAERS, DOD has conducted three efforts to actively collect data that can be used to examine gender differences in adverse reactions after servicemembers have received the anthrax vaccine. The first effort, conducted by USAMRIID, included data on shots given at Fort Detrick during 1977-96. The second effort, conducted in 1999 by a DOD physician stationed in Korea, was a survey given to servicemembers when they reported for their initial six-dose schedule of shots; it asked questions about their reactions to the previous shot. Results from this effort reflect the researcher's preliminary analysis of the data. The third effort, conducted in 1998-99 at Tripler Army Medical Center, Hawaii, included a survey on adverse reactions to the first three shots when individuals reported for their fourth shot and later included a follow-up survey on adverse reactions to the fourth shot. None of the efforts used a control group. Also, all three relied on self-reported data and were not adjusted for factors such as occupation, physical activity level, and age. Because of differences in the way data were collected, reaction rates are not strictly comparable among the different efforts. According to the data gathered in all three efforts, a higher proportion of females reported reactions to the anthrax vaccine than did their male counterparts. Tables 1 and 2 summarize the rates of reported reactions to the vaccine during the two efforts at Fort Detrick and in Korea. The researchers at Fort Detrick determined that the statistical difference was significant [10] in the reported reaction rates of males and females after their second and subsequent shots. The researchers for the other two efforts did not report whether the difference in reported reaction rates was statistically significant.

10 Tests of significance deal with the question of whether a difference is real or just a chance variation. It does not deal with the question of how important the difference is or what caused the difference. The test does not check the design of the study. If a test is significant at the 99-percent level, the results

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could be due to chance 1 percent of the time.

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Table 1: Gender Differences in the Reported Rate of Reactions to the Anthrax Vaccine, From Fort Detrick Data (1977-96)

Note: As a result of GAO's recalculation, the percentages reflect minor differences from those reported by the researcher.

a The gender difference in reported reaction rates is statistically significant at the 99-percent confidence level.

b The gender difference in reported reaction rates is statistically significant at the 99.99-percent confidence level.

Source: DOD.

Table 2: Preliminary Data on Gender Differences in the Reported Rate of Reactions to the Anthrax Vaccine, From Korea Survey (1999)

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our review, data on reactions to the third shot were not available.

Source: DOD.

The data gathered in Korea shows that after the first two shots, more than twice the proportion of women reported the systemic reactions of fever, malaise, or chills than men (see table 3).

Dose number
Males percent
(number of doses)
Females percent
(number of doses)
First 3.75 (1,013) 3.86 (259)
Second 3.06 a (979) 7.29 a (247)
Third 1.71 a (938) 5.06 a (237)
Fourth and subsequent 3.40 b (5062) 7.06 b (737)
Dose number
Males percent
(number of doses)
Females percent
(number of doses)
First 42.1 (2036) 71.6 (495)
Second 44.4 (1953) 74.0 (474)

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Table 3: Preliminary Data on Gender Differences in Systemic Reactions, From Korea Survey (1999)

Note: This represents a preliminary analysis of the data by the researcher, and at the time of our

review, data on reactions to the third dose were not available.

Source: DOD.

The Tripler effort also demonstrates gender differences in reported reactions (see table 4). These data show that a higher proportion of women reported making an outpatient visit after a vaccination than their male counterparts. In addition, more than twice the proportion of women reported that they missed one or more duty shifts after their vaccinations than did males.

Numbers in percent

Fever Malaise Chills

Dose

number Male Female Male Female Male Female

First 0.9 2.8 6.0 15.6 1.5 5.5

Second 1.7 4.8 7.1 15.4 1.9 4.0

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Table 4: Gender Differences in Reported Local Reactions, Outpatient Medical Visits, and Missed Duty, From Tripler Army Medical Center Survey (1998-99)

Note: Between 421 and 471 men and between 74 and 83 women responded to each question on the survey.

a Data were not available.

Source: DOD.

Numbers in percent

Reaction Dose 1 Dose 2 Dose 3 Dose 4

Moderate to severe redness

Male

Female

17.5

49.1

20.4

46.9

17.2

51.4

31.6

39.8

Swelling of lower arm

Male

Female

9.7

13.4

9.5

13.5

9.2

13.0

7.1

8.4

Pain limiting motion of elbow

Male

Female

9.7

17.1

8.7

13.5

7.6

11.7

7.9

8.6

Localized itching

Male

Female

25.2

62.6

25.7

60.4

24.5

57.9

27.7

39.2

Lump or knot

Male

Female

63.9

89.9

64.4

87.8

60.5

83.6

65.5

73.2

Muscle soreness

Male

Female

66.6

79.7

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64.7
76.4
61.8
70.8
60.4
61.6
Outpatient medical visit
Male
Female
5.3
10.0
2.0
13.8
2.7
3.9 a
Missed one or more shifts of duty
Male
Female
2.2
5.0
2.0
5.1
0.9
3.9 a

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Status of Federal Efforts to Develop a Second-Generation Anthrax Vaccine

According to researchers and the Institute of Medicine of the National Academy of Sciences, the current anthrax vaccine has several disadvantages.[11] The amount of protective antigen in the vaccine is variable from lot to lot because the manufacturing process cannot precisely quantify the antigen.[12] Also, there is some evidence that the current

anthrax vaccine may have diminished efficacy against certain virulent strains of anthrax (Bacillus anthracis). And the required six-dose schedule and annual boosters complicate the logistics of inoculating all of DOD's troops and increase the cost of the vaccine program.

According to DOD research, a second-generation recombinant vaccine created with a process that is fully defined, quantified, and controlled in terms of protective antigen, can be developed and that fewer doses could be required.[13] DOD research also shows that a recombinant vaccine could be created using modern techniques to produce highly purified protective antigen. This process not only would remove unwanted bacterial proteins but also would enable precise amounts of the purified protective antigen to be incorporated into the vaccine. A further potential benefit is that, compared to the current vaccine, the protective antigen could be produced in a nonspore-forming organism. As a result, according to DOD officials, manufacturers could use their buildings and equipment to produce the anthrax vaccine as well as other vaccines.

In 1995, USAMRIID developed a new recombinant protective antigen vaccine against anthrax. This vaccine was successfully tested in experiments using animals but has not been tested on humans. USAMRIID officials stated that this testing would take about 3 years, and FDA approval of the manufacturing of the vaccine could take years longer. DOD considers further development of this vaccine candidate an unfunded requirement. In response to the perceived threat of bioterrorism, the

11 P.S. Brachman and A. Friedlander, "Anthrax," Vaccines, ed. S.A. Plotkin and E.A. Mortimer, Jr., (Philadelphia: W.B. Saunders Company, 1994), p. 737, and Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response, Institute of Medicine (Washington, D.C.: National Academy Press, 1999), p. 135.

12 Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response, Institute of Medicine (Washington, D.C.: National Academy Press, 1999), p. 135.

13 B. Ivins et al., "Immunization Studies with attenuated strains of Bacillius anthracis," Journal of Infection and Immunity, vol. 52 (1986), pp. 454-458; B.E. Ivins, "The Search for a New-Generation Human Anthrax Vaccine," Clinical Immunology Newsletter, vol. 9 (1988), pp. 30-32; and Y. Singh et al.,

"Study of Immunization Against Anthrax with the Purified Recombinant Protective Antigen of Bacillus anthracis," Journal of Infection and Immunity, vol. 66 (1998), pp. 3447-3448.

Department of Health and Human Services' National Institute of Allergy and Infectious Diseases formed a working group to develop and test a second-generation anthrax vaccine. The Institute recently funded several active research grants in this regard.

In developing a second-generation recombinant anthrax vaccine, researchers believe they will need to address the additional problem of whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine. A variation in virulence among anthrax strains and a variation in relative resistance to vaccine-induced immunity has been observed in experiments on animals. However, the reasons for the variation have not been scientifically proven.

Mr. Chairman, this concludes my formal statement. If you or other members of the Subcommittee have any questions, we will be pleased to answer them.

Contacts and Acknowledgments

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Mr. SHAYS. Thank you very much.

Major General Claypool. Thank you.

Gen. CLAYPOOL. Chairman Shays, Representative Schakowsky, Mr. Tierney, it really is a pleasure to appear before this committee, and I would like at the beginning to acknowledge the first panel. I truly do recognize that they are heroes and it took a great deal of courage for them to come before this group to testify.

I really think this kind of openness that your hearing is provoking is indeed one of the things that help make America great. And from the standpoint of the department in terms of its encouraging individuals to come forward, in the department policy, of course, is that individuals who have concerns about their health care and health-care system should come forward with their own individual complaints and we will do what we can to solve them and fix that.

Mr. SHAYS. Could I just interrupt you a second to thank you for making that statement. And also to thank you for not objecting to having the military personnel speak first and that you were here for two-plus hours to listen to them.

That is not always usual. Sometimes people of your rank, out of protocol, say, I would like to go first. So, on behalf of all three of us, I appreciate, one, your being here, and second I appreciate your statement.

Gen. CLAYPOOL. We found it very illuminating, actually. And it has been a long time since my kids say that I was a real doctor. So the opportunity to sit and listen to individuals with their medical problems was very illustrative to me, and I would like to offer to any of them that any of us on the panel here, the DOD members, that can help them get access to the evaluation or care that they need—it looks like they are already plugged into the right system. But we will do our best to do so.

Mr. SHAYS. Thank you.

Gen. CLAYPOOL. I would like to focus the testimony initially on five points about our program that I would like to emphasize. No. 1 is that we know that anthrax exists this very day as a weaponized agent in arsenals of countries hostile to the United States. And as such, it presents a clear and present danger to the U.S. forces around the world.

No. 2, the cornerstone of our defense against this biologic agent is the anthrax vaccine, which has been licensed by the FDA for nearly 30 years. The vaccine has an excellent safety record and is highly effective.

Three, to date nearly 300,000 service men and women have received nearly 1 million anthrax immunizations. And while side effects do occur in some people, they tend, and I say, they tend to be temporary, confined to an area around the injectionsite and mild or moderate in most people.

In this age of no-notice worldwide deployments, immunizing the total force is the only way to assure force protection against this biological warfare agent, which, in the form it would be used against us, is as deadly as the ebola virus.

And fifth, this is not a medical program. It is a commander's program to prevent combat casualties and keep our forces ready for battle. It is also a program for our soldiers, sailors, airmen, Marine,

to fulfill our national obligation to do everything in our power to keep them safe and free from the consequences of biologic war.

A number of studies listed in our written statement have shown that the anthrax vaccine is a safe vaccine with an incidence of adverse events that is comparable to other commonly used vaccines.

On either side up here, there is a histogram that depicts several vaccines, both new and old vaccines, and I think there are sort of three points to take from this chart.

No. 1, systemic complaints such as headache, fever, joint pain, fatigue, are common kinds of system complaints that we see with the anthrax vaccine as well as the commonly used vaccines.

Second, the incidences of these side effects to the anthrax vaccine is comparable of that to the Lyme vaccine, diphtheria, tetanus and pertussis, which is a common child immunization agent, the typhoid vaccine, as well as hepatitis A.

The third interesting observation is, you can see—Colonel Gerber made these slides, and I think he challenged my vocabulary for knowledge of color—but one very tall vertical bar, which I guess I will call turquoise, shows fever. With the exception of fever, I think the other interesting feature is the fact that the Lyme placebo, the placebo immunization used in the Lyme product, shows a significant incidence as well.

And so we expect to have system effects, not uncommonly, with a number of vaccines. And the anthrax vaccine is comparable to those.

It is important for everyone to understand that any vaccine carries with it a degree of risk. And the decision whether or not to use this particular agent, as we have heard, must be based upon an analysis of weighing the risks from the side effects against from the risk from the disease the vaccine will prevent.

In the case of the anthrax vaccine, the scales of balance are clearly tipped in favor of its use to protect our military forces.

Furthermore, in the case of protecting the entire force against anthrax, the risk versus risk decision is not one that can be left to the personal choice of each service man or woman. An analogy is that the risk versus risk decision for childhood diseases results in several mandatory vaccinations for schoolchildren. This is because the risk of not immunizing presents a public health threat that extends beyond personal health concerns.

In the military, the risk of not immunizing affects the capability——

Mr. SHAYS. Excuse me. Just hold off 1 second.

[A series of vote buzzers go off.]

Gen. CLAYPOOL. It's not an anthrax attack, I assume. [Laughter.]

Mr. SHAYS. My astute counsel said that is six bells.

Gen. CLAYPOOL. Now, could I bargain for a little more time to talk, or is that—[laughter.]

Mr. SHAYS. What we are going to do is have you finish your statement, and we are going to have a few others so we may get a little lunch break here. We will see. But let's have you finish your statement.

OK?

Gen. CLAYPOOL. Yes, sir.

Mr. SHAYS. Thank you.

Gen. CLAYPOOL. The point I was trying to make is the risk of not immunizing presents a public health threat that extends beyond personal health concerns, and for the military, the risk of not immunizing affects the capability of the entire military unit and the success of the military mission.

Secretary Cohen and General Shelton said it more succinctly when they wrote, "Our commanders must know that all, not simply some fraction of their forces, are protected from this biologic threat. Soldier, sailors, airmen, and Marines fight in teams. And they need to know that all team members are protected from the anthrax."

While we are aware of isolated, unexplained persisting systemic conditions that have appeared in relation to the administration of the vaccine, we are not aware of any pattern of long-term side effects from the anthrax vaccine.

As is typical for other vaccines licensed at the time the anthrax vaccine was licensed, the FDA did not require long-term studies to be conducted after licensure was awarded. The standards for recently released vaccines include provision for post-marketing evaluation.

As we have gained additional experience with this vaccine, we have come up with questions of our own, the answers to which we feel would allow us to improve an already excellent vaccine. And so the Department is convening at the end of this month a team of military and civilian experts to design a set of studies to better evaluate the long-term safety of anthrax vaccine as well to answer some of these questions which we have raised.

We are conducting these additional studies of the FDA-licensed vaccine to conform with present-day, post-marketing practices. It is important for all of us to establish every reasonable degree of confidence in the minds of Americans, who are all stakeholders in this important force health-protection issue.

I would like to spend a minute talking about how we collect data, that is about passive surveillance versus active. One kind of surveillance is active surveillance in which all of them, or more commonly, a cohort, are evaluated as to whether or not they have had any side effects from the vaccine. This is a tool that is often used in post-marketing situations.

It would be labor-intensive, cost-prohibitive, and would not conform to civilian expectations for us to use this in all 2.4 million service personnel whom we will administer the vaccine to. It is one method we have used in some of our studies and will use in cohort manner in our ongoing studies.

Another type of active-surveillance method advocated by the CDC in post-marketing evaluations is the large, linked data base. DOD will utilize this approach in our research efforts through accessing our immunization tracking program's data base, the DEERS system, and through the large medical data base residing at a tri-service defense medical surveillance system here in the National Capital region of the Walter Reed installation.

Passive surveillance is a common surveillance method employed for the collection of adverse events. We know that it does not give a picture of the total number of adverse events, but it does provide a large pool of vaccine recipients from whom we can collect information regarding the emergence of spontaneous or infrequent reac-

tions whose low numbers would otherwise slip through a focused active surveillance system.

DOD uses a passive surveillance system developed collaboratively by the FDA and CDC called the VAERS system. DOD requires its providers to report through the VAERS system all cases of loss of duty of more than 24 hours, hospitalization for any reaction, or suspected contamination of the vaccine lot.

However, it encourages all health-care professionals to report all adverse events that they consider important and clinically relevant, even if they don't meet the aforementioned criteria.

It is also important to mention that patients themselves are encouraged to and can input information into the VAERS system, and many of them have already done so.

The department has set up a process to have all VAERS reports, those reported by providers as well as by patients, to review by an independent external review panel, called the Anthrax Vaccine Expert Committee [AVEC]. The AVEC consists of a special panel of experts from the Health Resources and Services Administration, a component of Department of Health and Human Services vaccine injury compensation program.

The AVEC uses explicit criteria for attributing causality to adverse events coincidentally associated with the administration of anthrax vaccine.

As of July 1, 215 VAERS reports have been received, of which 174 have been review by the AVEC. They have found no pattern of causality stemming from the use of the anthrax vaccine.

In conclusion, the department is and will continue to be vigilant in our surveillance for any unexpected reactions to anthrax immunization. We are committed to fully investigating all concerns or all questions on the safety of anthrax vaccine, and will continue full and complete disclosure of all risks based on objective evidence.

We know anthrax kills immunization protects. We know death from anthrax is vaccine preventable, and that the Department of Defense has a safe and effective vaccine to protect its service members.

Immunizing men and women we place in harm's way to prevent death or a serious injury is our moral and ethical duty, a leadership responsibility we perform with great confidence. It would be unconscionable for us not to do so.

Thank you, sir.

[The prepared statement of General Claypool follows:]

RECORD VERSION

THE

ANTHRAX VACCINE IMMUNIZATION PROGRAM:

A Safe and Effective Vaccine Against a Clear and Present Danger

STATEMENT BY

Major General G. Robert Claypool
Medical Corps, United States Army
Deputy Assistant Secretary for Health Operations Policy

Submitted To

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Introduction

Chairman Shays and Distinguished Committee Members, I am honored to appear before your Committee today to address your questions about the Department of Defense (DOD) Anthrax Vaccine Immunization Program (AVIP). I am Major General G. Robert Claypool, Deputy Assistant Secretary for Health Operations Policy. I am accompanied today by Rear Admiral Michael L. Cowan, Deputy Director for Medical Readiness, Joint Staff; Colonel Frederick E. Gerber, Director, Health Care Operations, Office of the Army Surgeon General; and Colonel Renata J. M. Engler, DOD Ex Officio Representative to the National Vaccine Advisory Committee. At your request, our testimony will specifically address AVIP implementation, communication and medical protocols for deferrals and adverse events.

The Biological Warfare Agent Anthrax: A Clear and Present Danger

Our National Security Strategy places our Service Members in a posture of global engagement to **Shape** the international environment; **Respond** to the full spectrum of crises; and **Prepare Now** for an uncertain future. The strategic deployability of our Armed Forces places our men and women at significant risk from the proliferation of biological weapons. Anthrax clearly tops the annual intelligence threat lists from a host of hostile countries known to have stockpiles and the offensive ways and means to deploy anthrax against our forces. Regional, transnational, asymmetric threats and proliferation of biological weapons grows each year. We face a clear and present danger from anthrax.

Death is the predictable outcome of inhalational anthrax in unvaccinated persons. Once clinical symptoms appear, death is assured, despite the most heroic, state of the art, post-exposure medical intervention and treatment given.

Death from anthrax is vaccine preventable. Immunization with Anthrax Vaccine Adsorbed, licensed as safe and effective by the Food & Drug Administration (FDA) in 1970, provides our men and women with their only chance of survival. Experienced reviewers at the FDA found Anthrax Vaccine Adsorbed (AVA) safe and effective in preventing anthrax in human beings. Anthrax vaccine serves as the cornerstone of our Force Health Protection countermeasures to this lethal threat.

Key Implementation Principles: Safety, Communication, & Individualized Care

Chairman Shays, as you requested, my testimony will focus on the DOD programs to assess and assure the safe delivery of anthrax vaccination. I will review our multi-faceted vaccine safety surveillance programs and discuss our comprehensive communication programs to explain the value of anthrax vaccination to Service Members and their families.

Coordinated Surveillance for Anthrax Vaccine Safety

The Department of Defense conducts an aggressive, multi-faceted surveillance program to assess vaccine safety. In fact, the safeguards of vaccine administered to DOD personnel meets or exceed every standard for vaccine administration to the civilian population. Our program includes a wide variety of activities that can be grouped into three main scientific method categories: clinical studies of vaccine recipients; database analysis of vaccine recipient automated medical records; and spontaneous reports.

Each of these scientific methods has advantages and disadvantages. As the Centers for Disease Control & Prevention (CDC), the FDA and trained epidemiologists discovered over time, these methods need to be used in tandem, to fully understand whether or not an adverse event was caused by a vaccine or merely coincided in time with the vaccination. Coincidental events are sometimes referred to as temporal (pertaining to or limited in time) associations. Temporal association alone does not prove causation.

DOD follows the convention of CDC, FDA, and the nation's public health and epidemiologic specialists in distinguishing adverse events and adverse reactions. Adverse events are adverse outcomes, for which a cause-and-effect relationship with an exposure (to a medication or vaccine) has not yet objectively been determined. An ***adverse event*** becomes an ***adverse reaction*** once objective evidence is available to establish a cause-and-effect link between an exposure and an adverse outcome. Table A lists some of the criteria proposed many years ago by famed epidemiologist Sir Austin Bradford Hill that help us make the

determination of causal association.

Table A: Causal Association Criteria

Adapted from: Rothman KJ, Greenland S. Modern Epidemiology, 2nd ed. Philadelphia: Lippincott-Raven, 1998:24-28.

The CDC publication, *Epidemiology and Prevention of Vaccine-Preventable Disease*, 5th ed., January, 1999, discusses the most reliable and conclusive ways to establish causal relationships for vaccine adverse events — and they are relatively few. Causal links between a vaccine and an adverse event may be established if they produce a unique laboratory result, a unique clinical syndrome, or an epidemiologic study shows vaccinated persons are more likely than unvaccinated persons to experience the adverse event.

Let me now review the three scientific method categories of evaluation which address collection of information on adverse events: clinical studies, database studies and spontaneous reports (passive surveillance).

Clinical Studies

Clinical studies are active studies that follow all individuals in a defined population to determine their responses to vaccination. They are expensive and time-consuming. Good clinical studies are often narrowly focused. Great care must be taken in designing clinical studies to avoid pitfalls that epidemiologist experts call *selection bias* and *recall bias*, among others. The challenge is to design a study that eliminates *alternative explanations*. As described below, numerous clinical studies have been conducted on the safety of the anthrax vaccine.

Licensure Safety Study

Studies on the safety of four lots of anthrax vaccine in the late 1960s, involving approximately 16,000 doses administered to approximately 7,000 people, were submitted in support of vaccine licensure to the National Institute of Health (NIH) Division of Biological Standardization (now the Center for Biologics Research & Review of the FDA) by the Communicable Disease Center (now the Centers for Disease Control & Prevention). With *active querying* and examination of vaccine recipients, *mild local reactions* (<= 3 cm) were reported after 3% to 20% of doses administered. *Moderate reactions* (> 3 cm to < 12 cm) were reported after 1% to 3% of doses. *Severe reactions* (>= 12 cm) were reported after fewer than 1% of doses. *Systemic reactions*, reported in four individuals (fewer than 6 per 10,000 doses), consisted of fever, chills, nausea and general body aches, which resolved spontaneously.

Brachman Study

Some of the original safety data on anthrax vaccine was collected through *active monitoring* of vaccine recipients from the Brachman study of 1,330 mill workers in the northeastern United States (*Am J Publ Health* 1962;52:632-45). Brachman showed that *mild local reactions*, consisting of 1 to 2 cm of redness, plus slight local tenderness, occurred in about 30% of recipients. *Moderate* local inflammation (a defensive reaction to irritation) (> 5 cm in diameter), occurred in 4% of recipients. More *severe* local reactions occurred less frequently and consisted of extensive swelling of the forearm, in addition to local inflammation. *Systemic reactions* (reactions beyond the limb into which the vaccine was injected) occurred in fewer than two per thousand (< 0.2%) recipients. These reactions included malaise and even less frequently, fever and chills.

Ft. Detrick Multi-Dose Safety Study

Starting as far back as the 1950s, 99 male laboratory workers at Fort Detrick, Maryland, were followed for up to 25 years, after being vaccinated against multiple diseases, including anthrax. These studies did not include a control group to study/compare adverse events in unvaccinated individuals, considered "the gold standard" today. While there were some minor elevations in liver and kidney function tests and white blood cell counts in these men (which cannot reliably be distinguished from the simple effects of aging), none of these men developed any unusual diseases or unexplained symptoms that could be attributed to the repeated doses of multiple vaccines [*Annals of Internal Medicine* 1965;63:44-57; 1974;81:594-600; *Bulletin of the Johns Hopkins Hospital* 1958;103:183-98].

Special Immunization Program Safety Study

In another clinical study begun in 1973, a study group of 1,590 people working in the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), received 10,451 doses of anthrax vaccine, as part of USAMRIID's Special Immunization Program (SIP). Based on visits to an occupational health clinic (the USAMRIID Special Immunizations Clinic), 4% of doses resulted in a *local reaction* consisting of redness, induration (an area of hardened tissue), itching, and soft or puffy swelling (edema) at the injection site. *Systemic reactions* of headache, fever, chills, malaise (discomfort, uneasiness), muscle and joint aches occurred after 4 per 1,000 doses. All *local* and *systemic* reactions resolved without any lost time from work, hospitalization or long-term effects. These employees continue to be examined and tested annually for medical conditions since their last visit, yet no diseases or unexplained symptoms have been observed that would not be expected in an unvaccinated group of

comparable age and other demographic characteristics.

Ft. Bragg Booster Study

In yet another DOD sponsored clinical study, USAMRIID investigators actively assessed the safety of booster doses of anthrax vaccine in 1992-93, given to 486 U.S. Army Special Operations Command soldiers at Fort Bragg, North Carolina, previously vaccinated against anthrax and botulinal (pentavalent) vaccine during the Persian Gulf War 1990-91. Of these soldiers, 21% had local redness and/or swelling in the arm where the booster vaccination was administered. In 5%, the redness and/or swelling was >= 5 cm. No reaction caused lost time from work or hospitalization and all reactions resolved without lasting consequences. One or more *systemic reactions* occurred in 44% of recipients during the first 30 days after vaccination, most commonly muscle aches (30%), malaise (16%), headache (16%), rash (16%), or joint aches (12%). We should note that these troops were engaged in a field exercise at the time of this study. Therefore, the role of the anthrax vaccination cannot reasonably be separated from the rigorous physical exertion (*alternative explanation*) commonly associated with Special Forces field deployments.

Canadian Forces Safety Survey

A Canadian sponsored, actively monitored study of vaccine reactions in 576 Canadian Service Members who received anthrax vaccine in 1998 revealed *mild local reactions* (<= 5 cm) after 9.5% of doses, *moderate local reactions* (> 5 to 12 cm) after 0.5% of doses, with no *severe local reactions* occurring. *Systemic reactions* occurred after 1.4% of doses. Five people developed a fever with or without chills, two reported transient (temporary) indigestion. One vaccine recipient reported a transient nerve disorder; and one individual reported having a persistent lump (nodule) at the injection site and multiple nodules at several distant sites, but it is unknown whether those lumps existed unnoticed before the vaccination.

USAMRIID Reduced Dose and Route Change Study

In another DOD sponsored pilot study, USAMRIID actively collected safety data during a pilot study to evaluate a reduced schedule for administering the anthrax vaccine (the current protocol requires administration of six doses, given at 0, 2 and 4 weeks and 6, 12 and 18 month intervals with an annual booster). The safety of the standard schedule of the first three doses (0, 2, 4 weeks) into the subcutaneous fat layer under the skin (a subcutaneous injection) was compared to two doses given subcutaneous and also compared to two injections into the muscle in the upper arm (an intramuscular deltoid injection), in a study totaling 173 people. *Systemic adverse events* were uncommon and their incidence did not differ among the three groups. After the first dose, the side effects noted were headache (14%); malaise (9%); loss of appetite (3%); nausea or vomiting (3%); muscle ache (3%); itching (3%) and low grade fever (3%). Redness and swelling at the injection site occurred more commonly among those given subcutaneous injections, compared to intramuscular injections. Male vaccine recipients developed injection-site reactions less frequently after subcutaneous injection (5% to 32%) than female vaccine recipients (39% to 66%), but the rates were comparably low for both genders when the vaccine was given by intramuscular injection (5% to 7%). Subcutaneous nodules, which resolved spontaneously, were common among recipients of subcutaneous injections, but were not observed among recipients of intramuscular injections. Subcutaneous nodules were usually not noticed by the vaccinee and resolved spontaneously. This pilot study provides compelling evidence that *local adverse*

events are less common when the intramuscular route is used to administer anthrax vaccine.

USAMRIID presented these preliminary findings to the FDA in December 1998, showing fewer doses by a less reactive route produce comparable levels of protective antibodies. The FDA requires an additional study of more than 900 anthrax vaccine recipients before it will consider to definitively assert the change in route and schedule is comparably safe and effective as the current route and schedule. This confirmatory trial is being planned at this time, under the sponsorship of the Joint Program Office for Biological Defense.

TAMC-600 Survey

The next study collecting data on the safety of the anthrax vaccine that I will describe is a prospective, population-based survey conducted at the Tripler Army Medical Center (TAMC), Honolulu, Hawaii. Called the TAMC-600 Survey, it included 603 TAMC personnel who are physicians, nurses, medics and other medical support personnel who augment U.S. medical forces in Korea in the event of military contingencies. Note that the people surveyed are a highly educated, medically experienced population who would be more able than the norm to describe any adverse events that might occur (and introduces a potential *population bias*). The objectives of this survey were to compare the TAMC data to previous studies and to evaluate the TAMC data against spontaneous reports submitted through DOD and FDA channels. Overall, the incidence of *local* reactions, specifically subcutaneous nodules and muscle soreness, are higher than previous surveys or studies, approximately 70% and 65%, respectively. *Systemic reactions* were not remarkably different from previous clinical experience. About 55% of vaccine recipients reported no *systemic* symptoms; about 20% reported symptoms that they personally judged could be ignored; 15% reported symptoms that affected their activity for a short time but did not limit their ability to perform duties; 8% reported symptoms that affected their activity for a short time that was relieved by self-treatment with nonprescription medication; and fewer than 2% reported that their symptoms were unrelieved by medication and that their ability to perform their duties was limited for a short time. In this group of vaccine recipients, the relative frequency of side effects for each of the first four doses was measured. The frequency of reports of muscle aches was roughly 15%, which represented the most frequently reported *systemic* complaint. The results for all *systemic* complaints did not substantially vary between dose #1, dose #2, dose #3, and dose #4. Muscle aches typically lasted between 7 hours and 3 days. In this group, three spontaneous reports (the FDA Form VAERS-1) were submitted and only one person lost more than one day of work and none were hospitalized.

USAF Vision Study

United States Air Force researchers are finalizing a multicenter pilot study of the effects of anthrax vaccine on visual acuity. The first phase of this study assessed 354 aircrew members vaccinated against anthrax and 363 unvaccinated aircrew members. Vision changes over the course of one year occurred in 12% of vaccinated crewmembers compared to 16% of unvaccinated crewmembers. This difference was not statistically significant. Additional data are being accrued to increase the precision of this analysis.

Comparison of Anthrax Vaccine with Other US Vaccines

The safety data on anthrax vaccine compare very favorably with safety data for other vaccines licensed in the United States. For hepatitis A vaccine, soreness at the injection site was reported by 56% of adult vaccine recipients. Headache was reported by 14%. For the typhoid polysaccharide vaccine, local tenderness was reported by 98%, pain by 56%, malaise by 24%

and headache by 11%. The pneumococcal vaccine has a 71% rate for localized soreness. The recently licensed Lyme disease vaccine produced localized pain in 93% of recipients and fever in 2.5%. The hepatitis B vaccine reports a *local reaction rate* of 17% and a *systemic reaction rate* of 15% in adults.

Each of these nine clinical safety studies alone, as well as all the studies in aggregate (totaling 12,574 people), supports the observation that *adverse reactions* associated with anthrax vaccine involve local, injection site reactions or minor, transient, self-limited, systemic events like malaise, muscle ache or headache. As important to note during the surveillance described above, no deaths occurred following doses of anthrax vaccine, nor any cases of severe allergic hypersensitivity reactions (known as anaphylaxis). The anthrax vaccine clearly has a side-effect profile comparable to other vaccines.

Additional Long -Term Study

The DOD leadership, its physicians and its research experts are confident of the safety and efficacy of the anthrax vaccine. Our leaders also respect the concerns expressed by a small number of service members about possible long-term health effects and want to address these concerns using the best, most appropriate scientific knowledge and practices. We will continue demonstrating an ongoing commitment to ensuring the health of our men and women as we implement the AVIP.

On July 29, 1999, the Anthrax Vaccine Immunization Program will convene a team of civilian and military medical experts to design a set of studies to assess the long-term safety of anthrax vaccine, in response to requests from Service Members, their families and recommendations of the General Accounting Office. In designing these studies, we will draw from the accumulated experience of some of the nation's best vaccine researchers at CDC and FDA.

A new long term study is also underway to determine whether individuals who received multiple vaccines, including anthrax vaccine, during their past employment at Ft. Detrick, MD demonstrated any adverse health effects over the long term. A total of 570 study and control volunteers have been enrolled in this case-controlled study begun in 1996. All volunteers signed an approved informed consent document. The study media included a 9-page health history questionnaire, extensive blood tests and urinalysis. The questionnaire queries mental and physical conditions of progeny as well as the health of volunteers. Study end points include symptoms, symptom complexes (including the Gulf War Illness complex of symptoms), diseases, abnormal laboratory and urine tests. Study subjects will be compared to 2-3 race, gender, and age-matched control subjects to determine if any long-term medical effects exist among this unique group of study subjects. Most study subjects received 150-200 vaccinations and skin tests; some received more than 300 such injections during their tenure at Ft. Detrick, MD. Analysis of the data from the extensive health history questionnaire and numerous laboratory tests is currently in progress.

Database Analyses

Database studies are active inquiries that can be completed more quickly than clinical studies, if data of interest have already been compiled in electronic databases. Database studies are only as valid and reliable as the quality of the data in the database. They are relatively inexpensive, after the investment in compiling the database is taken into account and they are

the one of the best means of assessing rare adverse events.

Following large-scale introduction of any vaccine after approval by the FDA, post-marketing surveillance of vaccine safety continues to be a concern. Passive surveillance methods for adverse events (discussed in detail later) have inherent limitations, principally, underreporting and recall bias. To address this, the CDC has noted that large linked databases (LLDB) are the most cost-efficient and rapid means for reliably conducting post-licensure studies of vaccine safety (*Epidemiology and Prevention of Vaccine-Preventable Disease*, 5th ed., January, 1999, p.285). For vaccines, these databases would include immunization records and medical outcomes information. DoD has both of these components in the Service's immunization tracking programs and the medical databases residing at the Defense Medical Surveillance System (DMSS).

The Defense Medical Surveillance System (DMSS) is coordinated by the Army Medical Surveillance Activity (AMSA), under the supervision of the U.S. Army Center for Health Promotion & Preventive Medicine (USACHPPM). The DMSS offers the capability to analyze hospitalizations, outpatient visits and other automated records for all active duty members. In coordination with the 29 Jul 99 AVIP convening of a long-term study panel, we intend to use the DMSS to measure the impact of anthrax vaccine, if any, on health outcomes among vaccinated Service Members, to see if it differs from unvaccinated Service Members. Plans are being developed now for more studies of this type, assessing both short-term and long-term questions of vaccine safety, as discussed in the previous sections. Because the data are collected prospectively on all active duty members, the problems of underreporting and recall bias are avoided and the epidemiologic power of the studies are maximized.

Having discussed the various *active* studies already accomplished and those we are planning, I will now explain our solicitation and analysis of spontaneous reports of *adverse events*, a *passive* form of surveillance.

Spontaneous Reports

Spontaneous reports are unedited reports of individual patient-clinician experiences. Clearly, spontaneous reports are rarely sufficient to assert that the risk of an *adverse event* is higher in a group of vaccine recipients than in a comparable group of unvaccinated people. CDC and FDA agree that spontaneous reports are important for generating signals of issues to address further, but spontaneous reports cannot ordinarily determine cause-and-effect directly. Spontaneous reports are uncontrolled, lacking comparison groups. Spontaneous reports are an important part of the national information-gathering effort to assess vaccine safety in general.

Vaccine Adverse Event Reporting System

The Department of Defense takes advantage of a National program for collecting spontaneous reports of *adverse events* coincidentally associated with vaccination. This program was developed collaboratively by the FDA and CDC and is called VAERS, the "Vaccine Adverse Event Reporting System".

VAERS is known as a *passive surveillance system*. Passive in this case means VAERS relies on the initiative of health care professionals and patients to report adverse events after immunization. I should note that VAERS reports, by definition, will include a combination of events caused by the vaccine and coincidences that are only temporally associated with immunization and have no cause-and-effect relationship with the vaccine.

Naturally, we are most interested in serious adverse events, but we are also interested in reactions at the injection site, often called "*local reactions*." DOD encourages our health care professionals to report all *adverse events* that they consider important and clinically relevant. As with our civilian clinician counterparts, the criteria for reporting a VAERS event are non-restrictive, as a means to encourage reporting.

DOD Joint Immunization Regulation

The duty to report adverse medication events has been codified for many years in the joint immunization instruction (Army Regulation 40-562, Bureau of Medicine & Surgery Instruction 6230.15, Air Force Joint Instruction 48-110, Coast Guard Commandant Instruction M6230.4E, dated November 1, 1995). The joint regulation requires submission of a Form VAERS-1 for all adverse events resulting in more than 24 hours of lost duty time or any period of hospitalization. These requirements represent a higher standard than in comparable civilian community health care settings. VAERS reporting is strictly voluntary for civilian health care providers. DOD VAERS reporting channels are depicted in Figure 1, below. The joint regulation is currently under revision and will clarify patient/provider roles, responsibilities, access to and reporting of Form VAERS-1.

DOD has have been consistent with CDC instructions to civilian health care professionals for VAERS reports and MedWatch (for reporting adverse events related to medications other than vaccines). Full and complete reporting of VAERS, MedWatch, and their predecessor programs has been the DOD policy for decades.

Copies of Form VAERS-1 are readily available at the pharmacy of every military medical treatment facility, as well as from multiple clinics and departments within the facility (e.g., pediatrics, internal medicine, immunization clinics, emergency department, etc.). Copies are found in the Physicians Desk Reference, a common reference in almost every practitioner's library. Further, we repeatedly advertise Form VAERS-1 can be downloaded from the Internet at the following addresses: www.anthrax.osd.mil, www.fda.gov/cber/vaers.html and at www.cdc.gov/nip/vaers.htm, as well as the VAERS toll-free number (800-822-7967).

DOD Form VAERS-1 Initiatives

Additionally, DOD emphasizes/encourages Form VAERS-1 reporting in the following publications/policies/initiatives:

u The Apr 99 updated DOD "Force Health Protection Against Anthrax Leaders Briefing", required to be given for all Service Members and DOD Emergency Essential Civilians by supervisors/commanders prior to receiving the anthrax immunization. Slides 12, 13, 14 clearly state for example, for both the AC and RC, "any vaccine associated adverse event may be reported through VAERS by either the patient of provider…in writing or by calling 1.800.822.7869…reporting instructions are available on the Internet at www.fda.gov/cber/vaers.htm."

u The Apr 99 updated DOD "Anthrax Vaccine Immunization Program Health Care Providers Briefing", slides 31, 32, 33 provide clear clinical guidelines for VAERS reporting in addition to the guidance provided in the Leaders Briefing above.

u DOD Policy Memorandum "Policy for Reporting Adverse Reactions Associated with the Anthrax Vaccine Immunization Program (AVIP)" created 30 Jun 98, issued 21 Apr 99 for Service coordination/implementation outlines clinical protocols and algorithms for submitting VAERS. This policy also requires submission of an "Anthrax Vaccine Adverse Reaction

Supplemental Form" in addition to the VAERS.

u DOD Policy Memorandum "Ensuring Reservists Have Full Access to Department of Defense (DOD) Medical Treatment Facilities (MTF) for Treatment of Adverse Events from DOD Directed Immunizations" staffed May 99, clearly outlines patient or provider submission of Form VAERS-1. The Memo will be accompanied by a Patient Information 'walk-away' brochure outlining facts about the anthrax vaccine, local and systemic reactions and adverse event reporting options, phone numbers, instructions, Internet access, etc.

u DOD Clinical Practice Guidelines for the Management of Anthrax Vaccine Adsorbed Adverse Events, were drafted during the 25-27 May 99 Annual DOD Conference for Biological Warfare Defense Immunizations. Over 150 personnel attended this AVIP Agency sponsored conference from the Services and Interagency participants (Centers for Disease Control and Prevention, Department of Health and Human Resources, Johns Hopkins University, Food and Drug Administration, George Washington University, Armed Forces Epidemiology Board, Joint Vaccine Acquisition Program, Center for Health Promotion and Preventive Medicine, US Army Medical Research Institute of Infectious Diseases, Government Accounting Office, etc.). The Guidelines outline clinical protocols, pre-treatments, specialty referral processes, contraindications, categorization of local and systemic reactions and associated treatment algorithms. The Guidelines clearly outline patient or provider reporting of Form VAERS-1 with all associated phone and Internet access numbers. After a synchronized staffing with the Services, Federal Agencies and other institutions, we will distribute the Guidelines worldwide, including posting on the www.anthrax.osd.mil web and all associated, linked health care sites.

u Form VAERS-1 reporting options, sources of information, downloaded copies of the form are a prominent feature of our newly revised anthrax website www.anthrax.osd.mil with separate hot button access to adverse reporting.

u The AVIP Agency's 1.877.GETVACC hotline, scheduled for 1 Sep 99 implementation will prominently feature patient or provider reporting of adverse events.

u The AVIP Open House/Speakers Bureau effort routinely addresses adverse event reporting, sources of information, etc.

u The AVIP Agency highlights VAERS reporting in their silent training aids product line in addition to other key themes such as dosing schedule, recording all vaccinations, threat, safety, efficacy, etc.

Non DOD Submission of Form VAERS-1

Individual Service Members or their family members are free to submit VAERS reports directly to FDA if they wish. However, this procedure has a number of disadvantages I would like to make you aware of. First, reports submitted by lay people may not be sufficiently detailed to allow grouping with similar reports causing potentially missed trends. Second, reports that go to FDA first, shared later with DOD, have information redacted. This redaction prevents DOD from categorizing demographic or geographic factors that otherwise helps us assess trends.

As you are well aware, several groups of reports of adverse events associated with anthrax vaccination have been reported Dover Air Force Base, Delaware and the 110th Fighter Wing, Battle Creek, Michigan. In each case, local medical officers redoubled their efforts to assure optimal VAERS reporting at their facilities. Reports from these facilities and all other DOD medical treatment facilities are included in the Form VAERS-1 Summary below.

Anthrax Vaccine Expert Committee

Once the VAERS reports are received at the central offices, an independent external-review panel we call the Anthrax Vaccine Expert Committee (AVEC) evaluates each report received. The AVEC represents a special panel of experts commissioned by the AVIP Agency in early 1998 to review and identify any signaling event that would identify problems stemming from the anthrax vaccine. These experts come from the Health Resources & Services Administration (HRSA), a component of the Department of Health & Human Services sponsored Vaccine Injury Compensation Program (VICP). To date, the AVEC has found no pattern of causality stemming from the use of anthrax vaccine. The AVEC uses explicit criteria for attributing causality to adverse events coincidentally associated with anthrax vaccination, based on work begun by the Canadian Advisory Committee on Causality Assessment.

Form VAERS-1 Summary

VAERS reports flow steadily and reliably through our analytic processes. To be consistent, we will report our findings as of July 1, 1999. As of that date, FDA received a total of 215 VAERS reports. Note that the number 215 are the number of Form VAERS-1 submitted. It does not correspond to a number of people in whom an event occurred. Nor does it refer to 215 events, because the same event may have been submitted through duplicate channels on separate reports, by different persons or advocacy groups encouraging mass reporting. Recognizing that the number 215 properly refers to Form VAERS-1 submitted, we will simply refer to them as 'Reports' or 'VAERS Reports' for the remainder of this discussion.

Of the 215 reports, 174 have been reviewed by the AVEC, up through their most recent meeting on 29 Jun 99. Of these 174 fully reviewed reports, 50 reported *local reactions* at the injection site only; 95 reported various *systemic reactions* only; 29 reported both *local* and *systemic reactions*.

You specifically asked about the frequency of VAERS reports among Service Members in the active (AC) and reserve (RC) components. As of 1 Jul 99, 153 VAERS reports involved AC members, 17 reports involved RC members, and four involved civilians. We report this data with a high degree of confidence although there is no block on Form VAERS 1 to specifically record AC or RC status. You recall that VAERS reports submitted directly to FDA have personal information redacted. These direct FDA submissions limit our ability to fully categorize the AC or RC component of the person reporting (i.e. some may be duplicate reports, unit of assignment is redacted, etc.). Thus, 88% were from the AC and 10% were from the RC. The reporting rates were 153 Form VAERS-1 from the 285,164 AC personnel vaccinated against anthrax (54 reports per 100,000 vaccine recipients); and 17 Form VAERS-1 were submitted from the 26,662 RC personnel vaccinated (64 reports per 100,000 vaccine recipients). The total reporting rate among RC personnel is only slightly higher than among active-duty personnel. None of the 17 RC generated reports involved hospitalization. Six of those 17 reports involved lost duty time. As expected, there is no indication that reservists are burdened with a greater risk of adverse events than their active-duty colleagues.

Eight reports discussed Service Members hospitalized with an illness coincidentally related to anthrax vaccination. Five have recovered completely. Among the five Service Members who recovered, the reports described the events as one case each of *Guillain-Barre' syndrome*, *multiple sclerosis*, *angioedema* involving the left jaw, *aseptic meningitis*, and severe *injection site inflammation*. Three of the eight Service Members hospitalized with an illness coincidental to anthrax vaccination have ongoing conditions: *bipolar psychiatric disorder*, *diabetes mellitus* and *systemic lupus erythematosus*. You will notice that the serious adverse events reported to date are all isolated cases. Only one of each condition was reported, with each condition being an event that also occurs among unvaccinated people. There are no reports of outbreaks of multiple cases of same disease, other than allergic-type (hypersensitivity) reactions, described below, that are expected with all vaccines and many medications.

The AVEC judged that there was no evidence that the ongoing conditions or the *angioedema* were caused by anthrax vaccination. The AVEC found evidence submitted through VAERS in the case of the alleged *Guillain-Barre' syndrome* was insufficient to reach a conclusion and they are awaiting receipt of additional information. For the cases of *multiple sclerosis*, *aseptic meningitis*, the AVEC judged the events were incompatible with a causal association and unrelated to anthrax vaccination. Notably, the AVEC judged the *injection site inflammation* event as the only case likely caused by the vaccine.

There have been three reports of serious illness coincidentally associated with vaccination that required loss of duty time greater than 24 hours. These reports involved *urticaria* (generalized itching) with hypersensitivity pneumonia, *spondyloarthropathy* (a vertebra joint disease) and *urticaria* with dizziness. The AVEC members judged the cases of *urticaria*, an allergic-type reaction similar to that seen in other vaccine studies, likely caused by the vaccine. The case of *spondyloarthropathy* aggravation was a pre-existing condition in the patient and classified "unclassifiable, not worthy of further review" by the AVEC.

The DOD uses a broader definition of serious adverse events, as we cast a broader net than the FDA definition of "serious." Twelve VAERS reports were submitted for Service Members who lost duty time greater than 24-hours, but were not hospitalized. These 12 reports outlined some of the following temporary symptoms: dizziness, nausea, fatigue, diarrhea, double-vision, abdominal pain, "flu"-like symptoms, urticaria, neck stiffness, abdominal cramps, inflammation at the injection site, migraine headache, mood swings and hair loss. Some of these events have been seen in other anthrax vaccine studies and are fully expected. Some are caused by multiple factors. The AVEC judged all these events "not serious".

Form VAERS-1 Recapitulation

To recapitulate, the AVEC reviewed 174 reports; eight reports reflected hospitalization and 15 reflected other "serious" events by either FDA or DOD definition. All the remaining 151 VAERS reports reviewed by the AVEC through 29 Jun 99 were not serious. That is to say, the remaining 151 reports were a mixture of expected skin reactions or transient flu-like symptoms due to the vaccine, or coincidental events the AVEC judged to be unrelated to vaccination.

The eight reports of hospitalization came from eight different geographic locations. Obviously, there is no geographic clustering of adverse events severe enough to warrant hospitalization. Similarly, the 15 other "serious" events by either FDA or DOD definition were not clustered by geographic location.

No VAERS reports were submitted regarding microbial contamination of vaccine lots. When the VAERS reports were compared to the lot of vaccine administered, there were no correlations between lot and number of reports received.

Education & Communication

The Department of Defense is committed to fully educating our Service Member population and their families on the purpose and value of anthrax vaccination in an unprecedented manner. We use each of the following communications media to accomplish this goal:

u A sophisticated anthrax specific website www.anthrax.osd.mil with multiple layers of information and methods for communicating with our Service Member population, their families, other DOD beneficiaries and concerned members of the American public.

u Three Service specific anthrax websites hyper-linked to all known military and civilian

websites discussing anthrax, biological weapons, health care, domestic preparedness, terrorism, VAERS reporting, preventive medicine, infectious disease, etc.

u Three Tri-fold information sheets individually tailored for Service Members, Family Members and Civilians. DOD issued Tri-folds to each Service Member receiving the vaccine since administering the first doses in March 1998. The Tri-fold explains the threat of biological weapons, the benefits of anthrax vaccination and the known risks from the vaccine. The Tri-fold is currently under revision to become a Quad-fold to include RC specific information on accessing care.

u DOD Leaders Briefing required to be given to all Service Members prior to receiving the anthrax immunization. Distributed by each Service and prominently posted on the www.anthrax.osd.mil website.

u DOD Health Care Providers Briefing given to all DOD health care providers administering the anthrax vaccine — who then serve as teachers, coaches, mentors for supervisors, commanders, Service Members and their families. Distributed by each Service and prominently posted on the www.anthrax.osd.mil website.

u Open House/Speakers Bureau briefings and open educational forums for all Service Members and their families.

u A 1.877.GETVACC telephone hotline scheduled for 1 Sep 99 implementation.

u A variety of anthrax vaccine 'silent training aids'. These highly visible training aids emphasize the key themes of the anthrax threat, safety and efficacy of the vaccine, adverse event reporting, etc.

u Armed Forces Information Service news media; local installation print, radio and television news service initiatives.

u A state of the art Anthrax Education CD-ROM which provides Service Members, families, supervisors, commanders and health care providers with tailored, multimedia information on the anthrax threat; safety and efficacy of the vaccine; signs, symptoms and prevention of anthrax. Under development for over nine months, the CD is scheduled for release in Sep 99.

u An Anthrax Vaccine Immunization Program Videotape explaining the threat, safety, efficacy of the vaccine. The video features prominent civilian and Government scientists and vaccine experts explaining and endorsing the vaccine. Under development for over six months, the Videotape is scheduled for release 19 Jul 99.

u DOD is currently collaborating with CDC to array this information in the format of Vaccine Information Statements (VIS) that civilian health care providers around the country give America's children, adolescents, and adults during routine vaccinations. Our DOD VIS is currently in draft with an expected implementation date of 1 Sep 99.

u Clinical Guidelines were drafted in May 1999, based on a consensus panel of civilian and military physicians experienced both in immunology and the general provision of health care. After a synchronized staffing with the Services, Federal Agencies and other institutions, we will distribute the Guidelines worldwide, including posting on the www.anthrax.osd.mil web and all associated, linked health care sites.

Guidelines represent DOD's concerted effort to standardize the evaluation and care of people who have adverse events after vaccination against anthrax.

Exemptions, Waivers and Deferrals Reporting

We refer to waivers and deferrals collectively as exemptions; within the category of *exemptions*, we recognize *temporary exemptions* (temporary delay from receiving additional doses of anthrax vaccine, such as during the course of an acute illness, pregnancy or similar short-term condition) and *permanent exemptions* (a long-term postponement from receiving additional doses of anthrax vaccine). Although the Services collaborate in designing the administrative and medical criteria for exemptions, each Service reports *exemptions* according to the needs of the individual Services. The U.S. Army can identify locally and centrally all doses administered, as well as all administrative and medical exemptions, in its Medical Protection System (MEDPROS) database. The U.S. Navy and U.S. Marine Corps can identify local doses administered using the Shipboard Non-tactical Automatic Data Processing Program (SNAP) Automated Medical System (SAMS), but does not collect information about waivers or deferrals. The U.S. Air Force tracks local doses administered, as well as exemptions, using its Military Immunization Tracking System (MITS). All four services transmit data to the central Defense Enrollment Eligibility Reporting System (DEERS) database.

Monitoring and Compliance Reporting

Monitoring and compliance using guidelines discussed in the preceding paragraphs are an ongoing quality assurance/quality improvement responsibility of both individual medical treatment facilities and the DOD military health system. Overarching guidance is established in a variety of ways, including standards printed in the joint immunization instruction, "Immunization and Chemoprophylaxis Regulation" (Army Regulation 40-562, Bureau of Medicine & Surgery Instruction 6230.15, Air Force Joint Instruction 48-110, Coast Guard Commandant Instruction M6230.4E), dated 1 November 1995. This regulation represents the current standard for immunizations and chemoprophylactic practices within the military health system. In addition to this joint regulation, each Service formal anthrax immunization implementation plan addresses clinical aspects of vaccine administration. Furthermore, we have begun additional programs to train health care providers before the next major expansion of the anthrax vaccine immunization program. In May 1999, the AVIP Agency sponsored the "First Annual DOD Conference for Biological Warfare Defense Immunizations" at Fort Detrick, Maryland, to allow a self-motivated group of clinicians the opportunity to discuss/review the AVIP and conduct a peer review of key clinical program elements.

Documentation

There are several other quality assurance/quality improvement measures commonly adopted in medical treatment facilities to ensure the highest clinical standards are fulfilled. All clinical encounters (e.g. immunizations administered, sick call visits, hospitalizations, etc.) are documented in the patient's health record (HREC). Each dose of anthrax vaccine is recorded in service-specific and DOD-wide tracking systems. The service-specific tracking system reports when a service-member is due the next dose or has been waived or deferred.

Clinical Panels

At the facility level, health care providers use panels called morbidity-&-mortality committees to discuss and investigate negative outcomes such as death (none of which have been reported to date from anthrax vaccination). Medical treatment facilities have pharmacy & therapeutics (P&T) committees to review and encourage reporting of all medication-related adverse events (including those involving vaccines). Treatment facilities submit reports of their quality

assurance/quality improvement programs to each Service medical headquarters for corporate review and analysis. To monitor and assure compliance, all Services report any adverse events weekly to their higher medical headquarters.

Inspector General Study

A DOD inspector general (IG) study begun Nov 98 is still underway to measure compliance with requirements to document anthrax vaccination. Data is still being collected and a final IG report is scheduled for October 1999.

Deployment Eligibility Guidance

We currently immunize Service Members assigned or attached to units deployed or scheduled to deploy to any of the ten high threat areas — presently the Arabian and Korean Peninsulas. This is an interim step. Eventually, anthrax vaccine will be given to all personnel

Guidance to Service Members, Emergency Essential Civilians and contractor personnel regarding deployment eligibility involving anthrax vaccine is found in:

u Each Service anthrax immunization implementation plan.

u In the DOD Country/Theater Clearance Guide

u In the "One Day Policy" issued 30 Mar 99 by the Secretary of Defense establishing a policy requiring anthrax immunization for duty in any of the current high-threat areas of one day duration or more.

According to the Service implementation plans for anthrax immunization, DOD policy states "a Service Member will be considered deployable if he/she is enrolled in the six shot series [received at least one shot], regardless of whether or not he/she has completed the series." In those rare instances when an individual is unable to take or continue the anthrax vaccination series due to medical or administrative reasons, as with all DOD vaccines required for worldwide deployment, the Service Member is still deployable. This condition is the clear exception to the rule. The DOD goal is to receive the first three immunizations (at 0, 2 and 4 weeks) before entry into high threat areas because of the high degree of protective antibodies conferred. This alleviates some of the complexities of having to vaccinate personnel in a high threat area while trying to focus on contingency operations. Anyone unable to comply with vaccination prior to deployment begins or continues the vaccination series upon arrival. Clearly the DOD objective is to begin vaccinating the Total Force in order to eliminate these deployment confounders.

Our National and Military Security Strategies are founded on a posture of global engagement and emergency response, often requiring no-notice or short-notice deployment of AC and RC units and individuals who deploy, fight and support as teams. DOD is committed to protecting Service Members and Emergency Essential Civilians and contractors with a full anthrax vaccination series. Our program is sufficiently flexible to allow for individual waivers and deferrals when in the individual's best interests, based on objective scientific, clinical expertise and operational requirements.

Conclusion

DOD conducted serious studies to assess the safety and efficacy of the anthrax vaccine. To date, there is no evidence of a pattern of serious, long lasting adverse reactions caused by the anthrax vaccine. The majority of personnel tolerate the vaccine without prolonged major side effects. There have been some individuals who experienced illness in temporal association with the vaccine. We are continuing to evaluate, treat and follow these patients. In view of the small numbers relative to the total population immunized, causality cannot be determined at this time. An independent panel of civilian academic experts, from some of America's best clinical institutions confirms our findings. I assure you, the Department of Defense is and will continue to be vigilant in our surveillance for any rare, unexpected reactions to anthrax vaccine. We are committed to fully investigating all allegations against the safety of anthrax vaccine and continuing full and complete disclosure of all risks, based on objective evidence. DOD will provide evaluation and care for any vaccine-related problems.

We know anthrax kills and vaccination protects. We know death from anthrax is vaccine preventable and that DOD has a safe and effective vaccine to protect its Service Members from the grave and urgent threat posed by weaponized anthrax. Vaccinating men and women we place in harms way to prevent death or serious injury is our moral and ethical duty — a leadership responsibility we perform with full confidence.

Record Version

ANTHRAX VACCINE IMMUNIZATION PROGRAM

Oral Statement By

Major General Robert G. Claypool

Deputy Assistant Secretary of Defense

Health Affairs (Health Operation Policy)

Presented To

Subcommittee on National Security,

Veterans Affairs and International Relations

Committee on Government Reform

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Chairman Shays, Representative Schakowsky and Distinguished Committee Members, I appreciate this opportunity to appear before your Committee today to address your questions about the Department of Defense (DOD) Anthrax Vaccine Immunization Program (AVIP). I am Major General G. Robert Claypool, Deputy Assistant Secretary for Health Operations Policy. I am accompanied today by Rear Admiral Michael L. Cowan, Deputy Director for Medical Readiness, Joint Staff; Colonel Frederick E. Gerber, Director, Health Care Operations, Office of the Army Surgeon General; and Colonel Renata J. M. Engler, Ex-Officio DoD representative to the National Vaccine Advisory Committee. At your request, our testimony will specifically address AVIP implementation, communication and medical protocols for deferrals and adverse events. Although we will focus our testimony primarily on the areas previously mentioned, I would like to begin by emphasizing a number of important points about our program.

- We know that anthrax exists this very day as a weaponized agent in the arsenals of countries hostile to the United States. As such, it presents a clear and present danger to U.S. Forces around the world.
- The cornerstone of our defense against this biologic agent is the anthrax vaccine, which has been licensed by the Food and Drug Administration (FDA) for nearly 30 years. This vaccine has an excellent safety record and is highly effective.
- To date, our Servicemen and Servicewomen have received nearly 1 million anthrax immunizations, and while side effects do occur in some people, they tend to be temporary, confined to the area around the injection, and mild or moderate in most people.
- In this age of no-notice, world-wide deployments, immunizing the total force is the only way to assure force protection against this biological warfare agent,which, in the form that it would be used against us, is as deadly as the Ebola virus.
- This is *not* a medical program – it is a line commanders' program to prevent combat casualties and keep our forces ready for battle. It is also a program for our soldiers, sailors, airmen, and marines – to keep them safe and free from the consequences of biologic warfare.

Since the purpose of this hearing is to focus on the general topic of adverse events, I would like to make a few comments at this time. A number of short-term studies, listed in our written statement, have shown that the anthrax vaccine is a very safe vaccine with an incidence of adverse events that is comparable to other commonly used vaccines.

For purposes of comparison, the studies of the current vaccine that were used at time of licensure showed that in 16,000 doses approximately 3-20% exhibited mild reactions and fewer than 1% severe side effects. In the case of hepatitis A vaccine, soreness at the injection site was reported by 56% of adult vaccine recipients. Headache was reported by 14%. For the typhoid

vaccine, local tenderness was reported by 98%, pain by 56%, malaise by 24% and headache by 11%. The pneumonia vaccine, which is a recommended vaccine for all Americans over the age of 50, has a 71% rate for localized soreness. The recently licensed Lyme disease vaccine

produced localized pain in 93% of recipients and fever in 2.5%. The hepatitis B vaccine reports a *local reaction rate* of 17% and a *systemic reaction rate* of 15% in adults.

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It's important for everyone to understand that any vaccine carries with it some degree of risk with its use. The decision whether or not to use a particular agent must be based upon an analysis of weighing the risks from side effects against the risk from the disease the vaccine will prevent. In the case of the anthrax vaccine, the scales of balance are clearly tipped in favor of its use to protect our military forces.

Furthermore, in the case of protecting the entire force against anthrax, the risk-versus-risk decision is not one that can be left to the personal choice of each Service man or woman. An analogy is that the risk-versus-risk decision for childhood diseases results in generally mandatory vaccinations for school children. This is because the risk of not immunizing presents a public health threat that extends beyond personal health concerns. In the military, the risk of not immunizing affects the capability of the entire military unit and the success of the military mission.

Military regulations require many different vaccines to be administered to military. None of these vaccines is voluntary; all are mandatory, and provide the basis for a lawful order. Secretary Cohen and General Shelton said it more succinctly when they wrote: "Our commanders must know that all, not simply some fraction, of their forces are protected from this biologic threat. Soldiers, sailors, airmen, and marines fight in teams, and they need to know that all team members are protected from anthrax."

While we are aware of *isolated* unexplained persisting systemic conditions that have appeared in relation to the administration of the vaccine, we are *not* aware of any pattern of

long-term side effects from the anthrax vaccine. As is typical for other vaccines licensed at the time the anthrax vaccine was licensed, the FDA did not require long-term studies to be conducted after licensure was awarded. The standards for recently released vaccines include a provision mandating post-marketing evaluation. And so, although some long-term experience has been gained as covered in our written testimony, the Department is in the process of convening a team of civilian and military experts to design a set of studies to assess the long-term safety of the anthrax vaccine. We are applying this modern standard to the established anthrax vaccine in response to requests from some Service members, family members, and from recommendations of the General Accounting Office. It is important for us to establish every reasonable degree of confidence in the minds of all Americans who are stakeholders in this important force health protection issue.

I'd like to now spend a minute talking about how we collect data, i.e., talk about passive surveillance versus active surveillance. One kind of active surveillance is where all recipients, or a cohort of recipients, are evaluated as to whether or not they have had any side effects from the vaccine. This is a research tool that is often used in post-marketing situations. It would be labor intensive and cost prohibitive to use this in all of our Service personnel. It *is* one method we have used and will use in our ongoing and long-term studies. Another type of active surveillance technique advocated by CDC in post-marketing evaluation is the Large Linked Database. DoD

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will utilize the Large Linked Database approach in its long-term research efforts through access to its immunization tracking programs database and though the medical database residing at the Defense

Medical Surveillance System (DMSS).

Passive surveillance is a common surveillance method employed for the collection of adverse events. We know that it under-reports the true number of adverse events but it does provide us a large pool of vaccine recipients from whom we can collect information regarding emergence of spontaneous reactions or possible reactions. The DoD uses a passive surveillance developed collaboratively by the FDA and CDC called the Vaccine Adverse Event Reporting System, or VAERS. DoD *requires* its providers to report through the VAERS system all cases of: (1) loss of duty for more than 24 hours; (2) hospitalization for any reaction; (3) suspected contamination of the vaccine lot. However, it *encourages* its health care professionals to report all *adverse events* that they consider important and clinically relevant even if they don't meet the aforementioned criteria. It is also important to mention that patients themselves can input information into the VAERS system and some have done so.

The Department has set up a process to have all VAERS reports, those reported by providers as well as patients, reviewed by an independent external-review panel called the Anthrax Vaccine Expert Committee (AVEC). The AVEC consists of a special panel of experts from a component of the Department of Health & Human Services' Vaccine Injury Compensation Program. The AVEC uses explicit criteria for attributing causality to adverse events coincidentally associated with administration of the anthrax vaccine. To date, the AVEC has found no pattern of causality stemming from use of the anthrax vaccine.

In conclusion, the Department is and will continue to be vigilant in our surveillance for any unexpected reactions to the anthrax immunization. We are committed to fully investigating all concerns or questions about the safety of anthrax vaccine and will continue full and complete disclosure of all risks, based on objective evidence.

We know anthrax kills and immunization protects. We know death from anthrax is vaccine preventable and that DOD has a safe and effective vaccine to protect its Service members. Immunizing men and women we place in harms way to prevent death or serious injury is our

moral and ethical duty — a leadership responsibility we perform with great confidence. It would be unconscionable for us not to do so.

Thank you for listening. We are now prepared to answer your questions.

Mr. SHAYS. Dr. Ellenberg, I think that we have three votes. The machine is going to close in about 10 minutes and takes about 8 minutes. I think what we will do is let people know that they can have some lunch or something, and we will start sharp at 10 of, barring they keep us on the floor. But I think we will be out before then.

So we will start sharp at 10 of. Is that OK with you? That's when we will start.

So we will reconvene at 12:50. We will recess, if you need to get some lunch or something. Let's do that.

[Recess.]

Mr. SHAYS. Call this hearing to order. And I think we have one remaining testimony from you, Dr. Ellenberg.

No, just slide that whole thing. Do you have enough room? It is kind of difficult there. Are you OK?

Ms. ELLENBERG. Yes, I think it is OK.

Mr. SHAYS. OK. Let me say, the bigger mic is not the one that amplifies. So—that's it. Thank you.

Ms. ELLENBERG. Mr. Chairman and members of the committee, I am Dr. Susan Ellenberg, director of the Division of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research at the Food and Drug Administration. I am accompanied by Dr. Miles Braun, a medical officer in our Epidemiology Branch. I appreciate the opportunity to discuss with you today FDA's Vaccine Adverse Event Reporting System [VAERS], which is designed to receive and evaluate reports of adverse events following vaccinations, and in particular, VAERS reports related to anthrax vaccine.

My written testimony is more detailed and I ask it be included in its entirety in the record. I would also like to say that we very much appreciate the testimony of those on the previous panel and wish to assure them that we will continue to review and monitor these reports and that we encourage anyone developing any medical problems following any vaccination to report those to VAERS.

Vaccines are among the most significant public health achievements of all time. They have been responsible for saving millions of lives and improving health worldwide and are extremely safe. Nevertheless, like all other medical treatments, vaccines are not entirely risk free. While serious complications are extremely rare, they can occur because vaccines are administered to healthy individuals and because of the virtual universal exposure of our population to different vaccines, it is important to identify even these very rare adverse reactions.

VAERS is a joint program of FDA and CDC. It receives reports from vaccine manufacturers, health professionals, State and local health clinics, and vaccinees themselves. To encourage reporting of any possibly vaccine-induced adverse event, the criteria for reporting to VAERS are deliberately non-restrictive. The system accepts and includes any report submitted, no matter how unlikely the connection with vaccination might seem.

Such reporting system——

Mr. SHAYS. I am going to ask you to slow down just a little bit. I think General Claypool was speaking a little more quickly because of the bell, but we have time.

Ms. ELLENBERG. We have more time. OK.

Such reporting systems are essential to the discovery of potential rare adverse consequences of medical products that may not become evident until many thousands or even millions of people have been exposed to them. There are important limitations, however, to the interpretations of the data collected by such systems, as I will discuss later.

VAERS receives 11,000 to 12,000 reports per year. About 15 percent of these reports describe a serious event, defined as an event that is fatal, life-threatening, requires or prolongs hospitalization, results in permanent disability, or, in the judgment of the physician, could lead to such an outcome in the absence of medical intervention.

Most of the remaining 85 percent of the reports describe self-limited transient events such as injectionsite reactions, allergic reactions, and fever, and such events as irritability and prolonged crying in infants.

Currently, all reports of serious events are followed up in detail by a health professional. Medical staff carefully monitor trends in adverse event reporting for vaccines. It should emphasized that adverse-event reports can be submitted by a health-care professional or a patient or anyone else. FDA protects the confidentiality of individuals reported to have experienced adverse events.

VAERS performs a critical function by generating signals of potential problems that may warrant further investigation. It is especially valuable in assessing the safety of newly marketed vaccines, but it is important to recognize that VAERS data alone are usually inadequate for drawing firm conclusions or providing a basis for regulatory actions.

Probably its greatest limitation is its inability to establish causality for most reports of serious events. This is because most of the types of serious problems reported to VAERS occur in unvaccinated as well as vaccinated individuals. When large numbers of individuals are vaccinated, some of them by chance alone will experience adverse medical events within a few days of vaccination.

For this reason, the fact that an event happens to occur shortly after a vaccine has been administered cannot by itself lead to the conclusion that the event was caused by the vaccine.

As of July 1, 1999, 215 reports of adverse events associated with the use of anthrax vaccine have been reported to VAERS. Of these, 22 are considered serious events, as defined earlier. These reports describe diverse conditions with no clear pattens emerging at this time. Some of these events are described in detail in my written testimony.

The remaining reports describe a variety of symptoms, including injectionsite pain and swelling, rash, headache, and fever. With the exception of injectionsite reactions, all of these reported adverse events can occur in the absence of immunization.

I will skip any comment on the Anthrax Vaccine Expert Committee, as that has already been described by the previous panelist.

While the date gathered from the VAERS system can serve as a useful tool in identifying potential problems, the reports on anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine. As more people receive the vaccine, the

number of adverse events reported will increase. The agency will continue to closely monitor and investigate these reports.

FDA continues to view the anthrax vaccine as safe and effective for individuals at high risk of exposure to anthrax. Vaccine safety is a high priority of the Food and Drug Administration.

I thank you for this opportunity to discuss VAERS and our efforts to monitor and ensure the safety of licensed vaccines.

[The prepared statement of Ms. Ellenberg follows:]

Statement by

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Department of Health and Human Services

Before the

Subcommittee on National Security, Veterans Affairs,

and International Relations

Committee on Government Reform

U.S. House of Representatives

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Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Committee, I am Susan S. Ellenberg, Director of the Division of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA or the Agency). I appreciate

the opportunity to discuss FDA's Vaccine Adverse Event Reporting System (VAERS), which is designed to receive and evaluate reports of adverse events following vaccinations, and its interface with the Department of Defense's (DOD) Anthrax Vaccine Immunization Program (AVIP). As requested by the Committee, I will provide an overview of the VAERS system, the evaluation and review of the information that is obtained through these reports, and the Agency's experience with adverse events reports for the anthrax vaccine.

The Importance of Vaccine Safety

Vaccines are among the most significant public health interventions of all time, and have been responsible for saving millions of lives and preserving health worldwide. Nevertheless, like all other medical products, vaccines are not entirely risk-free. While serious complications are extremely rare, they can occur. Vaccines are unique in that they are administered to healthy individuals and there is virtually universal exposure of our population to vaccines. Therefore, it is important to identify even these very rare adverse reactions.

Vaccine Adverse Event Reporting System

The Vaccine Adverse Event Reporting System (VAERS) resulted from enactment of the National Childhood Vaccine Injury Act of 1986 (NCVIA), 42 U.S.C. ' 300aa-1 et seq., as amended, which was aimed at improving childhood vaccine safety and mandated reporting of certain adverse events associated with vaccines. The NCVIA led to the creation of a unified national system to collect, manage and evaluate these adverse event reports. The VAERS system was initiated in 1990 and is jointly managed by FDA and the Centers for Disease Control and Prevention (CDC). VAERS receives reports from vaccine manufacturers, private practitioners, State and local public health clinics, and vaccinees themselves (or their parents or guardians). Certain of these reports are required to be filed under a mandatory reporting requirement. Vaccine manufacturers, however, must report to FDA all reports of adverse events of which they are aware.

Occasionally, reports are filed with the MedWatch system, which is FDA's larger adverse event reporting system for medical products other than vaccines. Adverse event reports to MedWatch involving vaccines are transferred immediately to the VAERS system, regardless of whether they originate by phone, fax or mail.

VAERS is similar in intent and operation to surveillance systems for other types of FDA-regulated products maintained by the Agency and to safety surveillance programs in other countries. While the motivation for creating VAERS came from the NCVIA, VAERS accepts all reports of suspected adverse events after administration of any U.S. licensed vaccine to individuals in any age group.

POST-MARKETING SURVEILLANCE SYSTEMS

VAERS is a "passive" surveillance system. This means that it relies on health professionals, patients or guardians to submit reports of adverse reactions following vaccination. (An "active" surveillance system, in contrast, would follow all individuals in a defined population to determine their responses to vaccination.) To encourage reporting of any adverse event suspected of being vaccine-induced, the

criteria for reporting to VAERS are non-restrictive. In effect, the system accepts and includes any report submitted, no matter how tenuous the possible connection with vaccination might seem.

These types of systems are essential to the discovery of potential rare adverse consequences of medical products that may not become evident until many thousands or millions of people have been exposed to them. While they are critical to FDA's post-marketing surveillance, there are important limitations to the interpretation of the data, however, as discussed below.

OVERVIEW OF VAERS ACTIVITIES

VAERS receives 11,000 to 12,000 reports per year. Approximately 15 percent of the reports describe a "serious" event, which is considered to be either fatal, life-threatening, or resulting in hospitalization or permanent disability. Most of the remaining reports describe self-limited, transient events such as injection site reactions, irritability, prolonged crying and fever.

All reports are entered into a computer database. Reports of serious events and fatalities are followed up individually by a health professional. Autopsy reports and other relevant medical records are sought and retrieved for review. Medical staff carefully monitor individual reports and trends in adverse event reporting for vaccines, with particular attention to newly licensed vaccines.

VAERS data are available to the public through the National Technical Information Service and also through requests to FDA's Freedom of Information office. Patient identifiers are removed from all data provided to the public. General information and the VAERS form itself are available on the VAERS Internet website. The website address is: http://www.fda.gov/cber/vaers.html.

OBJECTIVES OF VAERS

Spontaneous report-based surveillance programs, such as VAERS, perform a critical function by generating signals of potential problems that may warrant further investigation. As such, VAERS is the "front line" of national vaccine safety surveillance. It is especially valuable in assessing the safety of newly marketed vaccines. Careful review of reports during the initial months following licensure can provide additional assurance about the safety of a new vaccine, uncover previously unexpected events which occur when a vaccine is used in a larger and more diverse population than was studied in clinical trials, or rapidly identify potential problems not observed pre-licensure.

Although VAERS has methodological limitations inherent in passive surveillance systems, VAERS is essential to the U.S. vaccine safety monitoring system. It is the only surveillance system that covers the entire U.S. population and therefore includes the largest number of case reports of events temporally associated with vaccination in the U.S. It provides timely availability of data from a geographically diverse population, allowing rapid detection of possible new, unusual or rare adverse events. Such detection generates hypotheses that may then be tested in other databases.

Based on careful review, analysis and further investigation of spontaneous reports, FDA can initiate various actions: manufacturers' labeling or packaging change(s), conducting or requesting manufacturer-sponsored post-marketing epidemiological investigations (hypotheses testing in more rigorous databases); issuing a Safety Alert or "Dear Health Professional" letter, inspecting manufacturers' facilities/records, or working with a manufacturer regarding possible withdrawal of vaccine from the market (for safety or efficacy reasons). Keeping vaccine labeling/package inserts up-to-date is an ongoing, dynamic process that depends on new information gleaned from spontaneous

adverse event reports as well as other sources. Dissemination of safety-related information to healthcare professionals and the public is an important health goal of post-marketing surveillance.

LIMITATIONS OF VAERS

While assessment of VAERS data is often the first step in identifying potential new information about the safety of vaccines, it is important to recognize that VAERS data alone are usually inadequate for drawing firm conclusions or providing a basis for regulatory actions. Many reports omit important data and/or contain obvious errors that may not be easily identifiable or correctable. Multiple vaccines are frequently administered simultaneously, according to currently recommended vaccine schedules, making it difficult or impossible to determine which (if any) of the vaccines administered was the possible cause of the event. The extent of under-reporting of events occurring after vaccination is unknown, and the number of individuals in subgroups of interest (for example, infants) receiving the vaccine during specific time intervals is not known, so that incidence rates cannot be calculated. In addition, because VAERS accepts and encourages reports of all temporal associations, regardless of the rationale for the vaccine being the cause of the outcome reported, there is also "over-reporting" since many events reported, and entered in the database, are most likely not attributable to vaccination.

Probably the most important limitation of VAERS, as it is for any passive reporting system, is its inability to establish causality for most reports it receives. Adverse events occurring in unvaccinated individuals are not reported, so there is no "control group" to study. Most of the types of serious adverse events reported to VAERS can occur in unvaccinated as well as vaccinated individuals. Without an unvaccinated group it is usually impossible to assess whether the number of reported events is different from the number that would have been observed in the absence of vaccination.

Even if a vaccine is not the cause of certain rare medical problems, when a vaccine is used in a large population, it is a certainty that some number of these events will occur within a short interval following a vaccination. For this reason, the fact that an event --even a very serious event such as a death -- occurs shortly after a vaccine has been administered cannot by itself lead to the conclusion that the event was caused by the vaccine.

An adverse event can be causally attributed to a vaccine more readily if:

1. The event conforms to a specific clinical syndrome whose association with vaccination has strong biologic plausibility (e.g., anaphylaxis within 30 minutes after vaccination).

2. A laboratory result confirms association (e.g., isolation of vaccine strain varicella vaccine from skin lesions of a patient with rash).

3. The event recurs on re-administration of vaccine ("positive rechallenge").

4. A controlled clinical trial or well-designed epidemiological study shows greater risk of adverse events among vaccinated than unvaccinated (control) groups.

Because few of the serious adverse events reported to VAERS meet any of the first three criteria (one such example, however, is described below), and because clinical trials are almost always too small to provide useful information on rare events, methodologically more rigorous epidemiological studies must be conducted to assess causality for most serious adverse events that are investigated. A determination that the vaccine caused the post-vaccination event usually cannot be made on the basis of information acquired from individual VAERS reports.

CONTRIBUTIONS OF VAERS DATA TO UNDERSTANDING

VACCINE SAFETY

New Reactions

Several investigations of VAERS data have uncovered previously unrecognized problems that may occur rarely in vaccine recipients. FDA investigators noted occasional instances of life-threatening thrombocytopenias (low platelet counts) following the administration of MMR (measles, mumps, rubella) vaccine, a previously unappreciated level of severity of a known side effect. Other FDA investigators documented a series of cases in which hair loss followed immunizations (primarily hepatitis B vaccine), a rare effect not previously reported. Because some of these cases exhibited "positive rechallenge," as defined earlier, there is a greater level of confidence that these outcomes truly may have been caused by the vaccine. In another study, FDA staff identified a series of cases of severe injuries resulting from vaccination-induced fainting or syncope. These outcomes did not appear related to any specific vaccine, but were most probably attributable to the act of vaccination itself. Sometimes VAERS data may provide the useful and reassuring information that new problems have not been identified after additional experience with a vaccine, as with our review of reports for Hepatitis A and B vaccines.

Trends in Reporting

VAERS data also have been used to compare reporting patterns over time and investigate changes in reporting rates that might be due to changes in vaccine practices. For example, CDC epidemiologists reviewed reports of fever, seizures, and hospitalizations following administration of a newly licensed combination of diphtheria, tetanus and acellular pertussis vaccine (DTaP). The rate of such reports was about one-third lower than the reporting rate following the standard DTP vaccine, consistent with—and confirming in the context of general practice—the safety findings of the pre-licensure clinical trials.

ANTHRAX VACCINE

As we discussed in FDA's testimony before this subcommittee on April 29, anthrax vaccine was licensed by the National Institutes of Health's Division of Biologic Standards (the predecessor agency to CBER) in 1970 for protection against anthrax, a highly infectious and often fatal disease caused by spores of the *Bacillus anthracis* bacterium. Experience has shown that inhalation anthrax has a very high mortality rate, with estimates ranging from 80 percent to 90 percent or higher.

Since licensure, the anthrax vaccine has been used by livestock workers, veterinarians, lab workers and researchers at risk for infection, and more recently, as a preventive measure against a possible biologic weapons attack utilizing anthrax against U.S. armed forces. According to the manufacturer, from 1974 to 1989, approximately 68,000 doses of the vaccine were distributed. In 1990, approximately 268,000 doses were distributed. Between 1991 and the present, we understand that approximately 1,200,000 doses were distributed.

It is not possible to give a precise number of persons who received the vaccine prior to 1990. We estimate that between 1966 and 1971, approximately 7,000 at-risk persons received approximately 16,000 doses of the vaccine in a study conducted by the CDC. In addition, between 1974 and 1989, our files show approximately 68,000 doses were distributed. This is sufficient to vaccinate about 11,000 people with the full six-dose regimen of the currently approved anthrax vaccine. It is possible, however, that some doses distributed were not used, or that some individuals did not receive the full course of the vaccine.

Adverse Event Reporting for Anthrax Vaccine

FDA receives adverse event reports on the anthrax vaccine through a system similar to other adverse event reporting systems within the Agency. They are filed directly by health professionals as well as by patients or families. Reporting of adverse events associated with the use of anthrax vaccine is voluntary for individual healthcare providers but, as stated above, the vaccine manufacturer must report to FDA all reports of adverse events of which they are aware. It should be emphasized that adverse event reports can be made by a healthcare professional, a patient or anybody else. If a patient's physician does not file a VAERS report, the patient can do so. FDA protects the confidentiality of patients reporting adverse events. FDA encourages individuals to report to VAERS any clinically significant adverse event occurring after the administration of any vaccine licensed in the United States. Reports to VAERS may be made in writing or by calling a toll-free number, 1-800-822-7967. Reporting instructions are available on the Internet at http://www.fda.gov/cber/vaers.html.

CBER handles numerous inquiries from individuals concerning the anthrax vaccine. Individuals who believe they have experienced an adverse reaction are encouraged to report and provide information on filing a VAERS report. Forms are mailed and faxed to individuals upon request and individuals also are referred to FDA's website.

VAERS Reports on Anthrax Vaccine

Since the beginning of VAERS operations in 1990, through July 1, 1999, 215 reports of adverse events associated with use of the anthrax vaccine have been reported to VAERS. Of those, 22 are considered serious events, as defined earlier. These reports are for diverse conditions, with no clear patterns emerging at this time. Some of these events are described below. The remaining reports describe a variety of symptoms, including injection site edema (swelling with fluid in tissue), injection site hypersensitivity, rash, headache and fever.

The 22 serious events were reported to have occurred or been diagnosed at times ranging from 45 minutes to 4 ½ months after vaccination. Some individuals experienced adverse events following the first dose; others received up to 5 doses before event onset. Most of these individuals reporting adverse events during the current anthrax vaccination program have recovered. Five patients were hospitalized for severe injection site reactions. One individual experienced a more widespread allergic reaction. One individual was hospitalized with a confirmed case of aseptic meningitis nine days after vaccination. Two individuals experienced Guillain-Barré syndrome. Three weeks after receiving the vaccine, another individual was diagnosed with bipolar disorder and has not recovered. One individual experienced onset of multi-focal inflammatory demyelinating disease and has since recovered. Another individual experienced onset of lupus and has not recovered.

None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine to the event reported be entirely ruled out. It should be emphasized once again that it is not always possible to attribute a cause and effect relationship between a reported event and a vaccination. With the exception of injection site reactions, all of the adverse events noted above do occur in the absence of immunization.

While the data gathered from the VAERS system can serve as a useful tool in identifying potential problems, the reports on anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine. As more people receive the vaccine, the numbers of adverse events reported will increase. FDA continues to view the anthrax vaccine as safe and effective for individuals at risk of exposure to anthrax.

DOD's Anthrax Vaccine Immunization Program

FDA has not had an official role in the development or operation of the Department of Defense's (DOD) Anthrax Vaccine Immunization Program (AVIP), including the AVIP tracking system or the program's adverse event reporting system. In March 1997, DOD briefed FDA about their draft plan for the possible use of the anthrax vaccine to inoculate U.S. military personnel. Subsequently, FDA learned that the plan had been adopted by DOD.

Anthrax Vaccine Expert Committee

CDC was approached by DOD with a request to conduct additional reviews of adverse events reported for the anthrax vaccine. In July 1998, CDC requested that FDA participate in a program to evaluate VAERS reports for the anthrax vaccine. In response to the request by DOD, a group of non-government medical experts was convened in the fall of 1998 as the Anthrax Vaccine Expert Committee (AVEC). AVEC, which is coordinated by the Health Resources and Services Administration, has met six times since 1998. These experts have been reviewing all reports for the anthrax vaccine. Representatives of FDA, CDC and DOD attend meetings and FDA has provided information to assist the committee in its deliberations. AVEC is unique in that it provides an independent civilian expert assessment of adverse events reported for the anthrax vaccine.

Deployment of Partially-Vaccinated Service Personnel

The Committee requested that FDA "discuss the implications under FDA regulations of DOD policy declaring military personnel eligible for deployment to threat areas after only two of the six inoculations in the FDA-approved AVA immunization program." The Committee's concern centers on the question of whether a deployment before the full course of vaccinations is complete constitutes regulated activity.

FDA continues to view the anthrax vaccine as safe and effective for individuals at high risk of exposure to anthrax, when used in accordance with the approved labeling. That labeling calls for a six dose series of inoculations, with the initial dose followed by doses at two and four weeks, and at six, twelve and eighteen months. Data from the Brachman study submitted in support of licensure, and from CDC surveillance, suggest that individuals who receive less than the full series of inoculations may be at a higher risk of becoming infected than persons receiving the full series of doses.

FDA is not aware of any decision by DOD on deployability which postulates that less than the full course of six inoculations would provide full protection against anthrax. Because DOD has undertaken a program of full force protection against anthrax but has a continuing need to deploy service personnel in support of national defense, the issue of deployability involves a balancing of interests that is well outside of FDA's jurisdiction and expertise.

CONCLUSION

FDA evaluates the risks and benefits, both known and potential, for all FDA-regulated medical products. So far, the data gathered from VAERS reports on anthrax vaccine do not signal concerns about the safety of the vaccine. The Agency will continue to closely monitor and investigate reports of serious adverse events received on all vaccines, including anthrax.

Vaccine safety is a high priority of FDA and the Agency considers all of its safety programs, including

VAERS, as critical to carrying out its goals. Thank you for this opportunity to discuss VAERS and our efforts to monitor and ensure the safety of the anthrax vaccine.

Mr. SHAYS. Let me say to you, I have a number of questions that we have written down. I am going to follow the script somewhat cause these are very important questions for our study and I don't want to have my staff tell me later on that I should have asked that question and that we need to get it later.

So I am going to ask you, Mr. Chan, how does the number of shots affect adverse reaction rates?

Mr. CHAN. The six shots that are given over 18 months period—what we found based on the—first of all, there are differences between active monitoring and also passive surveillance systems.

Mr. SHAYS. Bring the mic a little closer to you.

Mr. CHAN. I am sorry.

Mr. SHAYS. Yes. Yes.

Mr. CHAN. For the three efforts that we mention in our testimony, I think we found that certainly the number of not only the number of adverse events increase as after the first one to the second one to the third one and so on, but also that there is a type of adverse reactions very similar. They are consistent, but really had not analyzed whether these things are significant or not. I think it does suggest though that, you know, DOD is pursuing looking at a possibility of reducing a shot out of those six.

Mr. SHAYS. I am not quite sure what your answer is. I asked, how does the number of shots affect adverse reaction rates. And your are not giving me a very clear answer.

The followup question was after which shot in the series do more people experience serious local or systemic reactions.

Mr. CHAN. Yes.

Mr. SHAYS. After which shot in the series do more people experience serious local or systemic reactions?

Mr. CHAN. Well, first of all, I guess, to answer this question, it's six shots, as we stated, was it was established in an arbitrary manner. OK, so from a scientific point of view, it went from a three-shot regimen through the animal study, whereupon they found that in applying to humans, they found that they had three cases of anthrax contracted.

So, that number has been raised from three to six, particularly in the early study, in 1962 of Dr. Brachman's work.

Mr. SHAYS. What GAO has done is basically look at what's on the table, the documentation on the table. And it is your testimony before this committee that the six shots is arbitrary.

Mr. CHAN. Yes.

Mr. SHAYS. That there is, what, no scientific evidence that six is better than three?

Mr. CHAN. What we were looking for was how was that determined in terms of is it based on the antibody to the antigen or protecting antigen, as we use, or is it based on a tradeoff between what is the difference in reaction, you know, in terms of the antigen level from three shots, to four shots, to five shots, and six shots and see which one came out with the right answer for you, looking for the optimum number of shots. And we didn't find that.

Mr. SHAYS. OK. Major General Claypool or any of the people with you, are you able to respond to that?

Gen. CLAYPOOL. I will take a crack at it. I mean, I think this is a vaccine, as we said, that is 30 years old. Back in the 1970's, when

it was submitted for licensing, we do think probably that—I think "arbitrary" may be a word that has boundaries to it. I mean, certainly we don't think you need to have 40 shots; we don't think one shot is sufficient. But six shots is what the FDA has, indeed, states, goes along with license assurification. And that is why we follow the FDA guidelines in our program.

Now we do believe that there may be a case to be made for fewer doses, and that is why we have developed a protocol, as I think you know, to look at reducing the number of shots. And we are currently working with the FDA to see if we can bring that into reality.

Mr. SHAYS. I am going to make an assumption, General, that you would welcome anyone else on your staff joining in.

Gen. CLAYPOOL. Yes, sir.

Mr. SHAYS. So I am not going to specifically ask. So, and I am also going to make the assumption that if we have slight disagreements that there won't be silence on it because, for instance, Admiral Cowan, if what General Claypool is saying, and you have some medical disagreement with that, I am going to assume that if you don't disagree, you agree.

Adm. COWAN. Yes, sir. Certainly.

Mr. SHAYS. OK. OK.

Col. ENGLER. Sir?

Mr. SHAYS. Yes.

Col. ENGLER. I thought I might be able to help clarify the answer to your question.

Mr. SHAYS. Thank you.

Col. ENGLER. All vaccines series, i.e., more than one dose, are based on some immunologic science of priming the immune system and then solidifying the immune response to create immunologic memory that will protect you long-term. And so it is a standard that many vaccines, you need more than one dose to optimize the long-term protective response to the vaccine.

And as that immune response enhances with booster doses, you will see more large local reactions. And some people who are genetically predisposed to be what we call hyper-responders, will make very robust immune responses, which many manifest in some systemic symptoms, like low-grade fever or chills that last only a few days.

Mr. SHAYS. So if you have someone who, Colonel, who has reacted negatively on the first one, it is likely that they will find it even more difficult with the second one, or the third, or the fourth?

Col. ENGLER. That is true in most vaccines, but in the old anthrax literature, it is described that the person who has a reaction—we are mainly talking about local reactions with dose one—may not have it with dose two, or may have it with dose two and not dose three. And in actual fact, the local and self-limited systemic reactions go down on the fourth dose, where there is a time interval of several months. And the immune system basically lowers again, because it is not being challenged.

Mr. SHAYS. You use the word "old literature"——

Col. ENGLER. I am talking about in the sixties.

Mr. SHAYS. Yes, that is old literature.

Col. ENGLER. For us, yes.

Mr. SHAYS. Given the kind of advances we make in medicine and with vaccines, that is old literature, but we have an old vaccine that we are dealing with. And it is basically your testimony that it doesn't always follow but that the answer—let me re-ask the question: Are you saying, in response to my question, that if you have an adverse reaction with the first one, that is not an indication that you might not have it, that it is an indication you are more likely to have it with followup?

Col. ENGLER. At the present time, we don't have clear data to that fact. There is some data, as I said, in the sixties' and seventies' literature that it is erratic. And so someone can have a very large local reaction with the first shot and it will be better with the second or completely gone with the third.

And the other pattern, where it does seem to worsen from shot to shot, is also observed.

Mr. SHAYS. OK. What's on the table is the GAO has basically said there is no evidence—excuse me, that six shots is an arbitrary determination and what Major General Claypool has said is that this is—they are following the FDA basic literature and not—excuse me, licensing. So let me have the FDA jump in here.

Ms. ELLENBERG. Well, I am not an expert on the anthrax vaccine. My understanding is that the original clinical trial that was done that supported licensure, in that study, the people who received partial vaccination, but not the full series, that some of those did develop anthrax, a small number. But nobody who was fully vaccinated developed anthrax. So that there is some suggestion there that more than some number of doses provides more protection. But it is based on a small number of cases.

That is the clinical data that I am aware of.

Mr. SHAYS. OK. Dr. Chan, why do passive surveillance systems result in adverse-event under-reporting?

Mr. CHAN. Well, it is a voluntary system, first of all. And this is not just the case with this particular case of anthrax vaccine. It is generally the case with most passive surveillance systems. And there have been a number of studies done to look at that, and in fact, even in applying it to the medical device where we found in GAO's own study found that less than 1 percent of the adverse events using medical device have been reported to FDA. This is post-1980's. And we found that is the case.

So that is the first point. The second thing is that if a surveillance system also has in place a sort of a filtering process whereby it requires individuals to determine whether it should be reported or not, then you have an added problem of, you know, reducing that total number.

And the third case is that, you know, a lot of people do not realize that this is really caused by the vaccine itself or whatever, and so they may or may not report it.

A passive system, in a way, it is a sort of sentinel system. You really don't try to figure out, is there a larger portion of adverse events that are occurring, but really what kind of event that is occurring.

So, if you decide that this is not something you want to report, then you lose sight of the fact that the intent of that system is to capture some extraordinary events that it is unexpected. And so,

I think, you know, in listening to the way this VAERS system is being applied for the anthrax vaccine, I think it suffers from a number of these deficiencies to reach this level of reporting that we find that's different in the active system that we have noticed.

Mr. SHAYS. Now, bottom line, that would indicate to me that the VAERS data should not be used as a source for determining adverse reactions rates.

Mr. CHAN. Exactly. And that is a pretty well-known fact. And certainly we have talked with experts in CDC who have done studies of this kind, and as we stated, the former Commissioner for FDA also noted the same thing, based on a 1997 study—1993 study, excuse me, to show that, you know, less than 1 percent of adverse events are reported.

Mr. SHAYS. Let me just have you put it—I am going to ask you the question this way, and I am going to go down the line here. Why shouldn't VAERS data be used as a source for determining adverse-reaction rates? I want you to tell me why it should not be used.

Mr. CHAN. Well, because of the fact that people——

Mr. SHAYS. You have already said it, I just want you to respond to the question as I have asked. So——

Mr. CHAN. Well, first of all, you need to track the number of shots given. That means the denominator has to be given, very clearly. Second, you need to have a system by which people do not under-report. OK? And third, it requires someone not screened out any possible other events that may be related to the vaccine. And ultimately, to follow through on those cases.

Mr. SHAYS. I don't understand the third one. Say that again. I didn't understand. I know you said it. I don't understand it. You will have to explain it to me.

You said, one, you need to track the number of shots. Two, you can't have under-reporting. Three, filtering? I don't understand filtering.

Mr. CHAN. What I am saying is that you should not, you know, theoretically you shouldn't have a criteria by which you set out and say this is our product insert, if these are the illnesses you have, then it is possible.

Mr. SHAYS. I see. OK.

Mr. CHAN. But if it is not, most likely it is not, so let's exclude that.

Mr. SHAYS. Let me put it in my terms. In other words, we make, we determine that only certain types of symptoms would be related to anthrax vaccine, and if there are these others, then those are filtered out because they are not, we don't accept them as being related. Is that what you meant by filtering?

Mr. CHAN. Yes.

Mr. SHAYS. OK. General Claypool, I am happy to have you defer the question to someone else, but I would like to ask whether you have confidence in the VAERS system?

Gen. CLAYPOOL. I have a great deal of confidence in the VAERS system to deliver what it is supposed to deliver. And what the VAERS system does, it provides, as we have said, the ability to look at spontaneous events or, No. 2, is to pull from a large data base to pick up infrequent circumstances. And as an example,

which I think is very timely today, and Dr. Ellenberg may be able to correct me, but, for instance, there is a new vaccine out for rotovirus in children, and this is a new vaccine. And it has been around a relatively short period of time. About 1½ million doses of this vaccine have been given.

Through the VAERS system, they have uncovered a cluster, I think that is six or eight cases of children who have gotten this vaccine who have developed a particular kind of small bowel obstruction known as intussusception. And so what this has done by this large data base with its passive reporting system has allowed the CDC to ask the question, you know, maybe we need to look at this data as to whether or not intussusception is a problem with the rotovirus vaccine.

So the VAERS system has allowed the identification, or the floating to the top, or the picking of this new problem.

Mr. SHAYS. OK, I am going to have my counsel—the committee counsel, rather—ask a question. But I just need to be clear, as I understand it. And the disadvantage is you are speaking to someone who is not expert on this issue. The advantage is, if I can understand it, the whole world can understand it.

And ultimately, we are going to get to that level. I was given three reasons why the VAERS system is not appropriate to, as a source of determining adverse-reaction rates. I was told, one, we need to track the number of shots. Two, we can't have under-reporting have it be valid, and we do have under-reporting. And we have a filtering system.

I would like you to respond to that.

Gen. CLAYPOOL. The VAERS system is only one piece of the equation. The other piece of the equation in terms of looking at adverse events has to do with an active surveillance system. And the department is engaging in plans to use two modalities of active surveillance. One of them, as I mentioned, is this large linked data base, which looks at linking the two large data bases we have from tracking the immunizations plus the Defense Medical Surveillance System, which is this large tri-service located at Walter Reed.

And the ability to look at these two sources of data that will allow us to identify people who have had the anthrax immunization and to track that with various kinds of complaints or problems that have occurred.

The other has to do with a cohort study; that is, to look at some of the studies we are planning to design, and actually have done, like the one at Tripler, where we do active surveillance, looking at a cohort of people to look for specific side-effect problems.

We can't do active surveillance on 2.4 million people. That isn't a common practice in civilian, where we would track every single individual. That would require us contacting them, you know, after each injection.

Mr. SHAYS. Yes, Admiral.

Adm. COWAN. If I could perhaps state that in a slightly different way. What you said about VAERS as the single way to track is absolutely true. It doesn't track the shots. It certainly will under-report side effects because it is voluntary and it could be a filter.

Back in the sixties, NASA taught us that if you want a system to run right, you make redundant systems within systems. And so

we have, as we have learned about this vaccine, we have been attempting to do that. We have a Hoffman survey and a Tripler study following a population of people. We know where they are; we watch them very closely. And we will end up with a statistically significant and accurate rate of the side effects, the adverse effects.

The business of filtering is a very big one, and I am glad that got touched on because it is the intent of the VAERS to find the unexpected association. Nobody had the slightest idea when swine flu came about that that would be associated with Guillane Barre. And they started popping up. It is not a natural association. You wouldn't have predicted it. And so we want the sentinel out there that guides us to the unexpected event. We want to do the measurements that tell us what the actual incidence of side effects is. And then we track the shots for the denominator.

We have got very good numbers on the shots. So all of these things packed together, we are gaining an ever-better sight picture of exactly what is going on with our population.

Mr. SHAYS. Thank you. I am just going to have the counsel ask a question.

The COUNSEL. Which leads to the question then, what is the adverse reaction rate for the anthrax vaccine. In planning the program from its initiation and planning it from here forward, what do you assume the reaction rate to be? Therefore, how many patients do you expect to see? How many allergists will you need to treat them?

Do you stick by the adverse reaction rates that are in the product labeling, or have we learned something different in these studies?

Gen. CLAYPOOL. You know, I think this entire anthrax vaccination program represents a continuum which we continually try to improve and make better. The product packaging, the information that comes with it, is based upon the licensing of the vaccine when it was given.

As we gather more information, we suspect, we feel confident we will come up with a better estimate as to what indeed reaction rates are.

As an anecdote, you know, at least three of us up here have had at least a total of five shots each. So there have been 15 shots given up here. If I were asked, if I were polled about whether I had a reaction, I would say, yes, my arm hurt; I really felt achy for a day. It swole up. I actually had trouble doing pushups because my arm was aching. And so if I were in an active system, I would be picked up as a mild local or maybe mild, even moderately systemic reaction because I felt sick after the one shot.

But I wasn't. I went through my duties. I went through the rest of the immunization series without any problem. So my entry was not recorded as an adverse system, as an adverse event.

So under an active surveillance system, these kinds of things would be picked up.

The COUNSEL. And you have already found that the rate of mild and moderate local reactions is higher than the product labeling indicates that. Correct?

Gen. CLAYPOOL. We say we have already found. We have done a number of different studies, and Colonel Gerber may be able to speak to them specifically. But we looked at different cohorts and

differing populations, and, depending upon, you know, how you are collecting the information, we do believe it will be higher. Yes.

The COUNSEL. And then, Dr. Engler, what is the, what can say, what is the relationship between a higher incidence of local reactions and any suggestions or conclusions about the incidence of systemic reactions? Is there a relationship between the two?

Col. ENGLER. If your are talking about short-term, self-limited, flu-like symptoms, low-grade fever, joint aches, muscle aches, as people's large locals increase, those may also be in tandem more frequent, reflecting the vigorousness of the immune response. And there are, at least in our experience and also in Colonel Hoffman's and Korea and the Tripler study, they resolve generally within less than 3 to 4 days, and some instances, for comfort, respond very well to non-steroidals, like Motrin or Tylenol.

Mr. SHAYS. Yes, Dr. Sharma.

Mr. SHARMA. Just, I want to make a few points here. First of all, in the product inserts, the adverse reaction rates that we see are from a different vaccine which has different contents and ingredients. And I think there is an issue that we had raised in our previous testimony; however, an assumption was made that the two vaccines are identical and, therefore, the adverse reaction rates would also be very similar. But this is an assumption which hasn't been tested.

Second, following the licensing of this vaccine, we really have very little information about its use. So we have no post-licensing experience with this vaccine. The only time we had was during the Gulf, when records were not maintained, and we don't know.

This is the first time you are using this vaccine, and if you compare the adverse reaction rates that DOD has presented based on VAERS, which is 0.007, and they are true, by that token, it is the safest vaccine. But when you look at the active surveillance systems, you see a range of reaction rates that, for some of these specific symptoms as many as 80 percent or 90 percent close to people are reporting some adverse reactions.

Now, I agree that a majority of them are temporary and would disappear, but it is striking the upper range.

And second, something that we didn't know before, because during the licensing phase, the clinic that the field trial that was done had some problem in the sense that individuals who were in that study had received both the vaccine, and a determination could not be made which of the reactions were attributable to the mark vaccine versus the current vaccine.

And second, and more importantly, the reaction-rate data could not be differentiated with regard to the gender. So they really didn't know how women were going to—what experiences women had. This is the first time we have learned from the active surveys that women are responding differently, reporting twice the rate, and I think this is a great revelation. And I think we would not have learned if we did not have such active surveillance systems. And this is the point that I just wanted to make it clear.

Adm. COWAN. If I could, sir, I would like to build on that just a little bit. I think that is exactly right. We took the best information we had off of the insert and the data that had been done when we started. And we advertised those as our adverse incidents. Ad-

verse incidents, to my mind as a clinician, come sort of in three flavors. There is minor local reactions or minor systemic reactions that are very short, self-limiting, don't require any, if only minimal, treatment.

If those become severe enough that they incapacitate a person that he has to be treated, needs something more than simple aspirin, then that is sort of another issue.

But those are reactions. And whether they are to the severe end or to the mild end, we expect those to resolve and not result in disease.

The thing that we are concerned about is the nasty surprise. The association of a type of disease that is caused by, that could potentially be caused by something like this that would pop up, we want to identify that as early as possible. And I think Dr. Sharma makes the case for having all these different kinds of surveillances and studies ongoing so that we learn very much up front from the numbers of people we vaccinate as we go, and we don't miss cases or have diseases go on or whatever, without knowing about it.

Mr. SHAYS. I am going to recognize Ms. Schakowsky, but I just was trying to think, when we talked about the arbitrary number of six, and we know that two is better than one, we probably can agree that three is probably better than two, but we are not quite sure, particularly from a military standpoint, they may ultimately recommend it be three.

How many shots, when I was in elementary school in the fifties, did I have in polio? Did I have one, and then one a year later, or something? I don't—I remember it was a dramatic event for me.

Adm. COWAN. Sir, mandatory vaccines for childhood illnesses are profuse.

Mr. SHAYS. Much different?

Adm. COWAN. Well, no. They are very much the same. There are ordinary vaccines like this is, but we started, probably most of us, about 3 months. There are probably anywhere between 8 and 12, depending on the State and the time, smallpox, diphtheria——

Mr. SHAYS. I had eight polio shots?

Adm. COWAN. No, sir. I don't know how many polio shots. Dr. Engler may have more information about that.

Col. ENGLER. It depends on what year. Do you remember getting the shots. You were in the shot series.

I don't know how young you are, sir.

Mr. SHAYS. What's that?

Col. ENGLER. I said, I don't know how young you are, sir. So you might not have received the——

Mr. SHAYS. What is—I was born in 1945, and so I just kind of remember them in the early 1950's.

Col. ENGLER. Yes, the inactive—at that time, there was the injectable polio——

Mr. SHAYS. It was injected.

Col. ENGLER. That means that it is the shot form as opposed to the oral. You may remember the sugar cube.

Mr. SHAYS. No. I had a shot. And I just remember not having a lot of them. I certainly didn't have six of them.

Col. ENGLER. Well, at age 2 months and 4 months and 6 months, you probably would not remember.

Mr. SHAYS. That was just a simple question. [Laughter.]

Ms. Schakowsky.

The record will note that I did not get an answer. [Laughter.]

That was simple.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I wanted to explore a little bit the difference of the reaction among women, and wondered if any of you have any information on why women might have more adverse and stronger adverse reactions.

Dr. Engler.

Col. ENGLER. I will certainly be happy to speak to that. It is well known in the science of immunology that immunologic responses of women in the antibody-producing side, are enhanced. And there is some survival value to that in that the mother transfuses her baby with antibody, and that is the first way that you defend your baby from infection after birth.

That also has the downside that 70 to 80 percent of auto-immune disease occurs in women. That is, when the immune system gets confused and inappropriately causes inflammatory destruction of self, of some organ, whether it is the thyroid or, in lupus, multiple organ systems.

Ms. SCHAKOWSKY. So the questions to Captain Piel or the comments that you are depressed, maybe you just want to have babies, that she perhaps needs counseling, were not really scientifically based, were they?

Col. ENGLER. Absolutely not. I think one of the challenges in health-care delivery, both in and out of the military, has been how women and their complaints presenting to the traditional medical system are handled. And I think we are certainly a long way away from where we were in that the experiences of Captain Piel are less frequent than they used to be, but education continues to be needed.

Gen. CLAYPOOL. I would like to say that each one of us was offended by that assertion. I mean that is not the kind of military system that we are part of, and that is not——

Ms. SCHAKOWSKY. Again, I want to say, General, that I appreciate what you said at the beginning, too, that you really encourage people to report adverse reactions and that you don't want to have a situation where people feel fear about it or feel that they will be intimidated.

When I was in the State legislature and there was a hearing on home-delivered meals, and I asked the presenter from the State, do we have any waiting list.

And they said, no, we don't have any waiting list. And then it occurred to me to ask, do we keep track of people who are asking? Do we know who is waiting?

And they said, no.

So, we don't want to be in that kind of situation that we have very few reports. And, in fact, we have testimony in the GAO report, which I had in front of me and now I don't—here we go—that a former FDA commissioner acknowledged the under-reporting of adverse events and passive surveillance and cited one study showing that, "only about 1 percent of serious events," attributable to drug reactions are reported to FDA.

Are we making any estimates about the percent of reported adverse reactions in this instance?

Col. ENGLER. That is a very widely quoted statistic, and I would just like to comment that we know that there can be substantial under-reporting to these systems. These are not good places from which to make estimates of rates because of that. But the under-reporting rate varies greatly, according to a lot of different things. Could relate to the newness of the product; it could relate to the seriousness of the event of the time after the administration.

There are data from the CDC that suggest with regard to vaccines that the more serious the event, the less problem there is with under-reporting. So I think it would not be accurate to assume that this 1 percent rate relates to medical products across the board. I suspect there is a great amount of variability.

Ms. SCHAKOWSKY. But still accurate to assume that it is greatly—there is a great deal of under-reporting.

Col. ENGLER. It is certainly accurate to assume that, I would say for most products, there is a great deal of under-reporting, but as the data from CDC suggests the under-reporting may not be so extreme for serious events after a vaccine. I suspect we get better reporting for vaccines than most drugs.

Ms. SCHAKOWSKY. Well, let me—as a result of the briefing that I received yesterday, I think I feel clear about what the benefit is to vaccinate against anthrax, that it is a threat and that in almost cases it would be fatal. So we want to—but in evaluating the risks, it seems yet appropriate to say, do we have to take as many risks as we do to achieve that benefit?

And one of the really disturbing pieces for me is the production of the vaccine itself and BioPort and its experience and whether or not we are getting the kind of product under the circumstances that we want from that company.

So just a couple of questions about that. Actually, I could have a lot of questions about that.

In a June 30th hearing held by this subcommittee, BioPort officials testified that its facility was closed after repeated FDA violations and that they were delayed in reopening by, ''unforeseen circumstances.'' And they suggested that some of the unforeseen circumstances included FDA's ''new'' requirements and evolving product standards.

So my question for the FDA is whether you implemented any new requirements since the DOD contract was signed 9 months ago that would not have been foreseen by BioPort and which would have caused this delay?

Ms. ELLENBERG. I'm sorry, that is just totally beyond my ability to respond. We will be glad to provide, to get to the right people and get that response back to you.

Col. GERBER. Ma'am, could I just interject, that you mentioned that BioPort, the predecessor or the aftermath of the MBPI plant, was involuntarily closed. I think it is very clear that BioPort closed their plant to reconstruct the production lines up there. They closed voluntarily on schedule to renovate the plant.

Gen. CLAYPOOL. It was not because of the FDA findings. I mean, it was part of the renovation to go ahead and address the renovation issue.

Col. GERBER. It was a scheduled closure to redo the production lines.

Ms. SCHAKOWSKY. OK. I guess what I will need, what I need to be convinced about is why it is that we have a single supplier that has had a history for problems dealing with the quality of the product in the past that has been shut down that has overestimated, underestimated by—is it—three times the cost that the taxpayer would have to expend on this, that has had enormous investment by the Department of Defense in terms of all the renovation, why it is that we want to put all of our eggs in what seems to me to be a fairly, given its history, unreliable basket.

And I don't know, I suppose the devil is in the details, but I would like to ask that general question.

Col. GERBER. Could I take a stab at this? You ask some very good questions that we ask ourselves: Why all our eggs in one basket? And we are working to resolve that.

I think there is a little interesting history here that when you go back to the vaccine industry here in the United States, back to the 1960's and 1970's, when there were 60 or 70 vaccine manufacturer plants in America. After some of the early polio vaccine, even the threat of a catastrophic lawsuit caused most of these vaccine manufacturers to close.

In fact, it is commonly known today that there are four, or only four, principal, major vaccine manufacturers, probably a dozen total. There is, again, the mere threat of a lawsuit is enough to cause vaccine manufacturers not even to get into that business. So——

Ms. SCHAKOWSKY. So we have immunized them against that. We have given them—they aren't liable for mistakes, according to our contract, are they?

Col. GERBER. If you are talking about the indemnification issue, you know, in 1976 we started with the swine flu, when the national swine flu vaccine, to indemnify that vaccine. But the fact of the matter, most vaccines under the National Childhood Vaccination Act are covered by Federal indemnification. So it is not an uncommon practice.

Mr. SHAYS. But the answer was yes.

Col. GERBER. Affirmative.

Col. GERBER. So that's just a little history. There has been no money in making anthrax in America, from the 1970's to the 19—to the modern anthrax vaccine program. BioPort, I understand, sold about 6,000 to 7,000 doses annually to veterinarians, laboratory workers, so on, and so forth. So there was really no need to have an additional vaccine plant.

Mr. SHAYS. Let me jump in if I could on this one and then I will give you back the floor.

Ms. SCHAKOWSKY. OK.

Mr. SHAYS. When, and this relates to the question of sole source. When did DOD begin work on a pure anthrax vaccine?

Col. GERBER. On a pure?

Gen. CLAYPOOL. I don't when they began to work on it, but there is ongoing work that sometime back in the early 1990's, at least probably 1993 or 1994, I'm guessing, is when the work began.

Mr. SHAYS. And when did you discontinue it?

Gen. CLAYPOOL. It hasn't been discontinued. It is still ongoing. I think what you are talking about is the recombinant PA vaccine.

Mr. SHAYS. General, could we be clearer on whether your definition of ongoing means that it hasn't been discontinued but it is going no where. Is this, is this, are we under active pursuit of a pure vaccine.

Gen. CLAYPOOL. Yes. Let me add. I would like to address that. I appreciate the opportunity to do that. Back in 1994, in about that time period, at that point, when we did not have an AVIP program to immunize the total force and we did have the current FDA-established vaccine and we didn't have the program we have in place and we didn't have the ability to have the total force immunized, we had an FDA fully licensed vaccine.

And so at that point, as you know Congress requires us to have fiscal responsibility for our programs, there was dialog and discussions, and at that time the best decision was made, since we had a fully licensed vaccine by the FDA, it may not make the most sense at that point to go ahead and continue with the development of a new vaccine, given all the other kinds of requirements that we have.

As you know, things have changed. We now have a total force immunization process, and so what we are doing is we are looking at ways to take this vaccine, and, if we can, go ahead and——

Mr. SHAYS. OK. So the answer really is, that we don't have an ongoing program for a pure vaccine right now. We discontinued——

Gen. CLAYPOOL. No, sir, that is not correct.

Mr. SHAYS. OK, we are going to pin this one down because this is really important. And let me just tell you where it leads me. We were Camar and Great Britain, where they were surprised, I think it is fair to say, that the United States made a determination to take an old vaccine with impurities under old technology that would probably not even get licensed today under FDA, and they were surprised that we sought to use this old vaccine when it was used for a few hundred a year and then ratcheted up to millions.

And the negative, obviously would be, by developing a pure vaccine, it would take time. The positive would be that it would be a pure vaccine and you wouldn't have as many adverse reactions.

And then this really gets to the point that Ms. Schakowsky is raising. It is my understanding that the pure vaccine does not have to be isolated, that it can be made in a plant where other vaccines can be made. And, therefore, you are more likely to have other players in this process. You wouldn't have to have just this sole—a facility just solely devoted to this.

So that is why I am going down this route. And what I think is on the table, honestly, and if I am wrong then we will let the record correct it, but it is important we be really accurate here. My understanding was, the DOD was pursuing a pure vaccine and made a determination that we need to act now, and the only thing we had on the table right now was this older vaccine.

So we made a decision that we would go with that. And it is my understanding that we are treading water right now in the development of a new vaccine. Treading water to me is basically going nowhere. And that is my interpretation, and if I am wrong, I want you to correct it.

Gen. CLAYPOOL. On Friday, this coming Friday, Mr. Dave Oliver, who had the opportunity to appear before your committee recently, has directed me to go ahead and convene a group of individuals that will help look at the question about the feasibility of bringing from farm to market, or bringing to production, this new capability. So I am having a task force that includes members from MR——

Mr. SHAYS. That's fair. That's fair. But that is different than what you said, it seems to me. That is saying that you are considering resurrecting this.

Gen. CLAYPOOL. Well, the research—excuse me, sir—the research has been going on. I don't know the details. It hasn't received a lot of funding, and it hasn't received a lot of priority on the list of priorities. But it hasn't been stopped, it hasn't been stopped.

Mr. SHAYS. OK.

Now this testimony is from when?

I would love GAO to jump in on this because I am looking on page 4, and you said: The vaccine was tested on animals, but clinical trials were not conducted in humans. DOD currently considers such a vaccine an unfunded requirement.

Gen. CLAYPOOL. Can we take that for the record and come back with specific numbers. I am going to get those.

Mr. SHAYS. Yes, I would like—we can get specific numbers, but I would like to have a sense of where we are at.

Gen. CLAYPOOL. I mean, me personally, I can tell you that I am, you know, because of the—I truly believe that in the environment in which the decision was made, when it was made, it was made with the best available information at that point. At this time, given the fact that Representative Schakowsky identified the fact that we have all of our eggs in one basket, not only with one producer but with one facility. And for national security concerns, many of us have wondered whether or not we need to have another facility just to be able to protect our source.

Mr. SHAYS. And that part is a valid concern.

Gen. CLAYPOOL. So, what I am saying is, is that I think the equation has changed. And because of that, I think it is important to look to see whether we can take this new vaccine, kick start it, jump start the basic research that goes to the tech base, that gets the production. And this is what we are trying to get at.

Mr. SHAYS. OK. I understand that, General. I am just—kick start means it wasn't started. And I just don't want us to quibble over terms. Whatever your understanding of the term and whatever my understanding is, in the end we have to have one sense of it. And I am not trying to put words in your mouth, but my sense is that we have a dormant program, and you want to kick start it.

And if my word dormant—if you want to elaborate on that, but let me first have GAO jump in because they were the ones who kind of introduced that concern. And then let me give you some time to think about what you want to say about it.

Mr. Chan.

Mr. CHAN. Let me try to answer this question. Give you a little bit of perspective here. Since the alternative issue has been raised about it. And then I certainly will ask Dr. Sharma to supplement it.

The way I understand it is that as far back as——

Mr. SHAYS. Talk into this mic here. OK? Turn it.

Mr. CHAN. Which way? This one? OK.

Mr. SHAYS. The bigger mic will pick it up, but the amplification is in this mic here. OK? Thank you.

Mr. CHAN. The way I understand it, as far back as 1988, the Department of Defense with health affairs had decided that they needed to pursue production of an anthrax vaccine, and at that time, clearly, MBPI was the only producer. And they were the ones that produced the vaccine for the Gulf war soldiers at the time.

In 1991, around September of that time, they decided to examine the possibility of having a second source to produce the vaccine, using the same manufacturing process as well as the same formula.

Mr. SHAYS. The old technology.

Mr. CHAN. Yes, and that is with NIH and PRI. That is how I understand it. But by 1993, they decided that they should not pursue this course of action even though the building in Fort Detrick had been prepared to supposedly produce such a vaccine.

Mr. SHAYS. You're not talking about creating a new vaccine.

Mr. CHAN. No. It is the same thing. I am just trying to give a perspective.

Mr. SHAYS. OK.

Mr. CHAN. Meanwhile, I think as late as 1980's, everybody had given some thoughts about it: This may not be the vaccine to go in the long term and experiments had been done. As we stated in our testimony that research had been done with a recombinant PA vaccine, which is pure and clearly would not have, possibly, impurities and have a much better control and so on.

Mr. SHAYS. Let me interrupt you a second.

Mr. CHAN. Excuse me.

Mr. SHAYS. Excuse me, I am interrupting you.

The advantage of a pure vaccine is you will have less adverse reaction, one, and two, my understanding is that you would be able to produce it in a plant that wasn't totally dedicated just to this vaccine.

Mr. CHAN. Exactly, the intent is to have a vaccine that is nonspore forming so that in fact it would be safe to produce it without dedicated building for that purpose.

OK. And as I understand it, and now may I quote General Blank, who told me that as of 3 or 4 years ago, they discontinued this effort to continue with, you know—so that is why we said there is no further clinical trials being done on this particular approach.

So our understanding recently is that HHS is thinking about pursuing this.

Mr. SHAYS. OK. But that is what is on the table, and then tell us where you think that is accurate and where you think it is not.

Gen. CLAYPOOL. Yes, sir.

Adm. COWAN. I will make one quick comment. I think we need to go back and find out exactly what is going on and bring it back to you. I do know there is an $18,000 bonus of money that has been given by the Joint Program Office for research in animal and assay validation studies. Those are ongoing now.

It is likely, upon termination of that, at this point in time, there are truly no more funds available for research going beyond there.

That should be resolved or get resolved at this upcoming meeting that General Claypool said.

But we will get the accurate information back to you.

Mr. SHAYS. Well, well—yes, Dr. Sharma.

Mr. SHARMA. Let me just sort of give you a little detail. In 1995, that was the last year funding was provided for the recombinant vaccine. At that time——

Mr. SHAYS. And the combinant vaccine is the new vaccine?

Mr. SHARMA. Right. And at that time——

Mr. SHAYS. Recombinant, I'm sorry.

Mr. SHARMA. Recombinant vaccine. All the basic R&D work was done and they were ready to go ahead for clinical trials. But since the funding was stopped and it was considered to be not, you know, a priority, the researchers stopped there.

Now, we had also spoken to the commercial manufacturers, because this was one of the issues that, you know, DOD was dealing with. And we wanted to know two things: their, you know, comments and reactions about the current vaccine or their assessment, and their willingness to join in the partnership with the Department of Defense or what their concerns were.

It is true indeed that the current vaccine requires the dedicated facility, but Merck and Lederle and American Home Products told us that if the Department of Defense would consider a recombinant vaccine, that they would consider production. One of the major difficulties is because they don't buy——

Mr. SHAYS. Let me just—we are getting off a little. I mean, what's on the table, I just want to nail down, is what I understand is—and you have helped answer, Dr. Sharma—but I think we are getting off a little here. The bottom line is we have the older technology in use, and that is the policy to use it. And we have a contract with a producer, the sole source.

And it is my understanding, based on the testimony of the GAO, that this is—the program to go to the recombinant anthrax vaccine is really basically on hold except, Admiral, for $18,000 continuing research, which in my judgment is practically insignificant to almost irrelevant but important you mention it, just so it is on the record.

And that, General, whether it is a glimmer in your eye or not, it doesn't make it an ongoing program. And so I think what is on the table is that we aren't able, we aren't actively pursuing that program as of now.

We may, and we probably should.

Col. ENGLER. Sir?

Gen. CLAYPOOL. Well I consider——

Mr. SHAYS. Now let me just say something. Before we all answer. The deeply—Admiral, I am sorry, General, I am sorry to interrupt you—but I just want to say to you that with no disrespect, we will keep going down this road if you want to, and I am happy to. But I am looking at the testimony today, and it seems pretty clear.

I don't want to suggest you shouldn't go further if you are comfortable, but——

Col. ENGLER. Sir, I would just like to add for the record that the assumption that a recombinant DNA vaccine will have fewer side-effect rates in terms of local reaction or systemic flu-like symptoms

is not necessarily true. The new recombinant DNA Lyme vaccine has a very high rate of both local-reaction side effect and systemic side effects. And there is a concern in regards to perhaps some people being at risk for auto-immune disease with that vaccine.

And we have, as an old vaccine person for many years, I can tell you some of the, "newer and better recombinant vaccines" have actually had higher local-reaction rates because of some of the other elements in—the concept that they are totally pure is not technically correct, sir.

Mr. SHAYS. OK. I don't want to—I realize and I think it is important to be technically correct, but as a general rule, is it not true that a newer vaccine is more likely to have benefits that will not have the side effects?

Adm. COWAN. Sir, I think we all agree that we should do this. I have—perhaps this can bring this to closure. Recently the National—this is one of the responses to the questions that you had asked in preparation for this. Recently NI—the National Institute of Allergy and Infectious Disease formed a working group on anthrax vaccines. NIH, FDA, USAMRIID were all there. Two meetings were held. The latest on February 19th. An NOU is being developed to develop this new vaccine. It is estimated that completion of phase one and phase two studies and a surrogate model for proof of efficacy could lead to licensure within 8 years.

So there is a current program. There is interagency development under way. We are not going to have all the information here, and so we will take the question. But it is under way, sir.

And we all agree we should do that.

Mr. SHAYS. General, did you have anything you wanted to say. Do you have anything you want to add to this.

Gen. CLAYPOOL. No, sir.

Mr. SHAYS. I interrupted you, and I apologize for not letting you finish. Is there anything that you wanted to add to this.

Gen. CLAYPOOL. No. I mean. I would repeat what Admiral Cowan has said. I mean, I think that I consider this a live program in the sense that we have been doing some things. Maybe we could do more; we intend to do more. It isn't a foregone conclusion that we will be able to come up with a product, even in 5 to 8 years.

In the meantime, the anthrax vaccine that we have, venerable though it is, is a safe and effective vaccine.

Mr. SHAYS. Just to make a point, this is an 8-year program, but had we started in real aggressively it would be 3 years to go, as my counsel has just whispered in my ear. And that is why he is next to my ear.

Mr. SHAYS. So. All right.

Mr. CHAN. Can I add a couple points here, somehow.

Mr. SHAYS. Sure.

Mr. CHAN. I think it is important. When we talk about the disadvantages of the current vaccine, one clearly was the production problem because of the spore form, and that limits you in terms of getting greater participation for competitive production of that vaccine.

It is the second major problem, which I wish, you know, that we should think about, is the fact that it is often used—the reason why we cannot have a vaccine, IND-approved and all that, it's be-

cause of the fact that we need human clinical trials. And we can't do that.

And the advantage, hopefully, with a new vaccine is that somehow you can, and as Admiral Cowan said, find a surrogate by which you can correlate that fact that using animal study to show that, in fact, it would give you the efficacy against humans, thereby bypassing the human medical trials.

I think that is the major advantage of something new, if that is doable. And they are looking into that, and there is some science behind it, how it can be done and so on. And certainly I think it is worthy of looking into because I think that is the other major barrier for developing a new vaccines.

Mr. SHAYS. Dr. Sharma.

Mr. SHARMA. I would just like to add, I think one of the difficulties, we are saying things here for which I am not sure we have complete evidence about its efficacy. Yes, it is true——

Mr. SHAYS. Sir, I am going to interrupt you a second.

[Chairman consults Ms. Schakowsky.]

Mr. SHAYS. Only one vote? Two votes?

I am sorry. Hold on 1 second.

[Consultation continues with counsel.]

Mr. SHAYS. I am sorry, we are going to be asking you to come back. I think that we need to nail these down. I know you all have been here a long time, but we are going to have two votes. We will continue for a few more minutes, but I can't let one go and then come back, because we still have two votes. So I apologize for that.

I am sorry, why don't you continue.

Mr. SHARMA. I think one of the problems with this vaccine is that, you know, as Mr. Chan mentioned about the lack of correlates, and when this vaccine was licensed antibody levels were considered to be a marker, but subsequently we have found that there is no relationship between antibodies level and protection. And that raises this whole issue about the number of the shots itself.

I mean, the whole premise of number of shots is that if you reach certain level of antibodies your body has, then it will protect you. So for that reason, if you can attain, you know, a certain antibodies level with two shots, you as much protected as with six shots.

And I think I have to really recognize Dr. Engler, who is in my view an excellent clinician and researcher and from whom I have learned quite a bit about the relationship between antibodies and their implications.

With the recombinant vaccine, in addition to developing surrogate markers for protection for which whereby we could certainly know for sure that the vaccine will work or not, it would also require fewer doses which certainly has, in the current vaccine, a clear indication that the more shots you give, and logically you would expect more reactions. So if you have fewer shots, and the researcher that we have spoken to at USAMRIID and in Camar in England, they certainly seem to believe that you could easily reduce the dosage to two, or at the most three. And that is quite a bit of improvement over the current vaccine.

Mr. SHAYS. OK. Let me—we have about 8 more minutes. Do you want to take about 5 minutes now and then come back or do you want to just——

Ms. SCHAKOWSKY. Well, unless you want to follow this——

Mr. SHAYS. Yes, I am going to be asking you to come back. And we are going to promise you that when we come back it will only be 30 minutes, at the most. So you can judge how much time you have left.

We have one vote, and then we have another. As soon as that other vote is over, we will come back. And we have a few more minutes if you want to just ask a few.

Ms. SCHAKOWSKY. I did want to followup on something that was brought up by the other panel, and I am not sure who the appropriate person would be to answer: the issue of the concept of waiver, and if anybody is allowed to have one, under what circumstances, do they exist. What's the policy?

Col. GERBER. If I could take that, ma'am. We refer to waivers and deferrals, as you had asked us in your question, Congressman Shays, we actually refer to those as exemptions. In the DOD we have permanent and temporary exemptions, your terms for waivers and deferrals.

In the DOD system, we have 11, I am sorry, 12 categories of permanent and temporary exemptions: 5 categories of medical exemptions and 7 categories of administrative exemptions. We are presently, all services inputting those permanent and temporary exemptions into the Defense Enrollment Eligibility Requirements, the DEER system.

The Army was the first to input those. The Air Force is inputting them now. And after the Air Force finishes, the Navy is the third scheduled in line to input their medical and administrative exemptions.

Let me just speak for the Army. That was the first in line or the first scheduled to dump their exemptions into the system. The Army, for example, records 5,779 exemptions in the system; 92 percent of those, 5,700 exemptions, are for administrative reasons. For example, a soldier has died. We want to take him out of the system so he doesn't count against compliance.

Ms. SCHAKOWSKY. That makes sense. [Laughter.]

Col. GERBER. The majority of those—well, the vast majority of those are, for example, permanent changes of station: A sergeant leaves my unit; while he is inbound to the next unit, I want him to come off of my rolls so I am not beaten up for non-compliance.

And then we have 8 percent of the remaining 5,700 exemptions that are there for medical reasons; 79 percent of those medical exemption categories are for a medical temporary pregnancy hospitalization or convalescent leave.

So, we are getting a very good handle on all the exemptions, both medical and administrative.

Ms. SCHAKOWSKY. So, if someone exhibits some kind of an allergic reaction or serious adverse reaction, are they ever eligible for an exemption?

Col. GERBER. Absolutely. I am going to ask Dr. Engler to expound on the medical aspect, but it is very common in our system when our soldier, sailor, airman, Marine comes in and requires

some sort of exemption. For example, he has had a heat injury or he has had a cold injury, we frequently write permanent and temporary profiles to limit their duty for temporary or permanent periods of time.

It is a very common experience, and I will ask Dr. Engler to simply comment on——

Ms. SCHAKOWSKY. Well, let me just—then Captain Piel could get, might be eligible or would be eligible for an exemption. Couldn't fly in those particular areas but would—could you explain this, it further?

Col. ENGLER. Yes. Anyone to any vaccine, travel vaccines and other vaccines that may be indicated or required for deployment, if there is a serious and persistent adverse reaction, and the majority of the adverse reactions that we see, we treat, and we continue the immunization with certain interventions or special approaches. So in that case, there is no need for a permanent medical exemption.

Really relatively rarely, if—and so none of these are filed until the work-up is completed and the treatment is done. And I think there may be some confusion in that initially a temporary exemption or temporary delay until the situation is clarified. And if then it is deemed that the benefit risk ration does not justify continued immunization, then there should be a submission of a medical exemption from that vaccine.

Mr. SHAYS. We have 4½ minutes until the time is out. And they will probably leave the machine open a speck longer. As soon as the next vote, we will vote, and we will come back.

And we will get you out in 30 minutes, even if we want to go further.

[Recess.]

Mr. SHAYS. I call this hearing to order again, and we are going to get you out very quickly. Let me start with you, Colonel Engler. And if you would tell me how many patients have you seen at Walter Reed—this is for Colonel Engler—how many patients have you seen at Walter Reed who present symptoms that may be associated with the anthrax vaccine?

Col. ENGLER. In terms of referrals for specific adverse reactions or prolonged?

Mr. SHAYS. Yes.

Col. ENGLER. At this point, from all over, and we have a wide referral base, we are—I don't have the exact number—but it is in excess of 40.

Mr. SHAYS. OK. How many have been sent from Dover Air Force Base?

Col. ENGLER. At this point, my department has, I believe, had six of those patients. And there are scheduled right now, the rest of them to come down, not just to see my department but other departments based on their symptoms.

Mr. SHAYS. And the rest constitute about how many?

Col. ENGLER. The 40 that I mentioned to you are independent of Dover.

Mr. SHAYS. All right. And then six——

Col. ENGLER. Then six from Dover to date.

Mr. SHAYS. And are you expecting more?

Col. ENGLER. Yes.

Mr. SHAYS. How many more?

Col. ENGLER. The plan that I was informed because—I would be happy to get specifics back to you cause I have been out due to the death of my mother—but the plan is that all of them will come to Walter Reed. If they have symptoms referrable to neurology or endocrinology they may not come to my department. So there is a centralized plan for Walter Reed to respond to anyone who has a problem.

Mr. SHAYS. I am very sorry to hear about your mother. Is this something very recent?

Col. ENGLER. Yes.

Mr. SHAYS. It's is good that you are willing to be here under those circumstances.

I just would like to ask you, is the number closer to 30 from Dover, because that is the number being bandied about?

Col. ENGLER. Again, I have been told that the spreadsheet that is being maintained has 31, but, again, it is plus or minus, please——

Mr. SHAYS. I know. Is there any commonality of symptoms in the patients you are seeing?

Col. ENGLER. No. There are maybe two patients that have overlapping symptoms, you know, two here, two there, but for the most part, they are distinct. What frequently, if you take the whole group, not focusing on Dover alone, we see an awful lot of the more severe large locals who have had flu-like symptoms that may have persisted for a week, and the question is, continuance or not.

Mr. SHAYS. Are the symptoms, any of them related to the same kind of symptoms we see in Gulf war illnesses.

Col. ENGLER. There are a few patients that I am aware of in detail that have overlapping symptomatology to Chronic Fatigue Syndrome and Gulf war illness-like symptoms.

As you know, the symptomatology with Gulf war is somewhat heterogeneous in that there isn't one single pattern of symptoms.

Mr. SHAYS. Let me just yield to the counsel.

The COUNSEL. Any commonality in terms of ears or, you know, audic nerves? We heard about ear infection before. There is a lot of reports about tinnitus and ear-ringing.

Col. ENGLER. Right. Ringing in the ears. In the spread sheet that we are compiling on those folks that we are seeing, I have a total of four patients who, as part of their symptoms, have had tinnitus. I would say that at least two of them are still being tested as to whether they have had some damage to their hearing just from the noise exposure, you know, occupationally that they have had. So that needs to be clarified.

But the patients have believed that their symptoms worsened with a repeated dose of anthrax.

Mr. SHAYS. Thank you. Doctor, General Claypool, how many immunologists does DOD employ or retain as consultants?

Gen. CLAYPOOL. I would have to check the records. I don't know.

Mr. SHAYS. OK. That would be a number we would like to have a sense of. When we dealt with the Gulf war illnesses, we found that illnesses related to chemical exposure, expertise in that area

was rather slim. And I would want the same for the allergists. How many you would employ as well.

Gen. CLAYPOOL. I will ask you a specific question. As immunologists, you mean—allergy and immunology is usually a conjoined or one flavor. So, we will come up with some numbers.

Mr. SHAYS. I think you get the sense of the areas that we would like. And we would like to just know if there is appropriate expertise or whether the military has the appropriate expertise in these areas and the numbers.

Sorry.

Col. ENGLER. I was just going to comment that I think we need to get to the numbers together cause they are in the research division, there are research immunologists who specialize in vaccine research. I am not privy to the exact numbers. And there are clinical immunologists who manage clinics.

Mr. SHAYS. The logic to it is, if we are going to have 2 million-plus, we are going to have some people who are going to legitimately have symptoms and some severe reactions. And do we have the expertise to cope with that. That is the basis for the question. And we will leave that on the table that you will get back to us on that.

Let me just as four more questions, unless there is a followup. Let me—Ms. Ellenberg, if you would, you have said, according to FDA, passive surveillance systems are essential to the discovery of potential rare adverse consequences of medical products that may not become evident until many thousands or millions of people have been exposed to them. That is from your statement.

And, is the FDA satisfied the DOD's surveillance efforts using VAERS is being implemented consistently and thoroughly enough to capture, ''signal events or unexpected adverse reaction trends?''

Ms. ELLENBERG. We don't have a way of monitoring exactly how this is being implemented. The plans that have been shared with us in terms of the reporting, the basis for reporting, should be able to get us reasonable numbers of what we would consider the serious events, if in fact all such events are reported. And we have been told that the criteria that were originally put forward are being expanded to include significant medical events.

Mr. SHAYS. But you do have some concern about the fact that this data is passive, it's not——

Ms. ELLENBERG. I wouldn't use this kind of a system to give, to come up with precise estimates of rates of adverse events. You really need, as has been discussed previously, a more active, more effort, a formal study to be able to produce those kinds of estimates.

Mr. SHAYS. Just as it relates, and I know that Ms. Schakowsky had asked the question, particularly as they relate to women, a number of them, but would you accept the VAERS data that says that women have twice the negative reaction that men do or——

Ms. ELLENBERG. Well, we can't make those kinds of estimates right now from the VAERS data. We have a relatively small number of reports. The actual—in our reporting system, there are more reports for men than for women. We don't know what the balance is in terms of who got the vaccine. So we really can't make those estimates from VAERS data.

Mr. SHAYS. OK. I am sorry. Dr. Engler.

Col. ENGLER. I just thought it might be helpful to the committee that the VAERS reports can be duplicative so that the numbers—you know, there could be two or three for the same patient, or if a person has a large local with mild flu symptoms for dose one, two, and three, those are three VAERS reports. So the frequency—it is not a system that will give you the data for the side-effect rates that we put in a vaccine information sheet or educate the patient about what to expect.

That is done with solicited surveys.

Ms. ELLENBERG. But actually, we do search for duplicates. The numbers that we are giving you, 215, were done after duplicate reports were taken out.

Mr. SHAYS. The challenge is that the VAERS gets attacked from both sides, but the DOD, you know, uses it as viable information. I mean, this is documents that you have. And so, it is just a little unsettling to me that we would base much of anything on it, frankly.

Col. GERBER. Sir, could I just add that the chart that you see depicted comes out of our office and what we are reporting is the rate of reporting. We are not using that chart to depict that that is the number of adverse reactions or events. It is the rate of VAERS reports submitted, the VAERS form dash one.

Mr. SHAYS. Well, you basically, in the chart, say 65 adverse reactions of 890,888 cases of vaccinations given, 0.007 percent. I mean, that is given to make people feel comfortable. And so, I think it is being used differently than you think it is.

This is a PR document in favor of the vaccine.

Dr. Braun, is there anything that you want to say. I find that people who don't participate sometimes have very cogent observations cause they have been listening instead of talking. [Laughter.]

No reflection on you.

Dr. BRAUN. Not at this time. Thank you for the opportunity.

Mr. SHAYS. I am going to assume that you are brilliant. [Laughter.]

Ms. ELLENBERG. That is why I hired him.

Mr. SHAYS. There is this wonderful picture of Attorney General Mitchell—this is off the record—when he was working with President Nixon, and he was described as the person who had created the new Nixon. And he was described as brilliant. And he never said anything. You just saw him sit in the biggest chair at the White House. And then one day we got to see him speak at Watergate, and we all had a different feeling. [Laughter.]

OK, you are on.

Why did I say that? [Laughter.]

I'm counting on you, boss.

Ms. SCHAKOWSKY. A couple of things that I would like given to me, one is, at an earlier hearing with different witnesses, I had asked for a list of the producers of vaccines that also get the same kind of indemnification. And maybe it is in the process to get to me. But I haven't gotten it yet. And the other is, I would like, Colonel Gerber, a copy of the waiver policy, and also you gave some statistics on who—not waiver, exemption policy. And I would like to see that and also some of the numbers associated with that.

Dr. Sharma, you had your hand up and I didn't get to hear what you had to say in regard to the issue of the differential between men and women in their effect. I wondered if you had some comments on that, on the gender issue?

Mr. SHARMA. Yes, I think this is significant because if you take a look at the percentages, we see two things. Overall reaction rate in both men and women is in these active systems significantly higher than what we had assumed it to be to date, and second, these findings about differences in genders have very specific implications about the dosing or over-dosing in women. And I think I would like to—I mean, there is nobody I know in this panel, perhaps there are, but at least I know Dr. Engler has tremendous expertise and we have talked to, and maybe she would like to comment on that. And she—I think it is more appropriate at this point.

Ms. SCHAKOWSKY. Thank you.

Col. ENGLER. I think the challenges of making a vaccination program like anthrax better as we learn and the science and immunology of female immune responses versus male is still somewhat in the growing phase. But we already know that inter-muscularly the anthrax vaccine, a large local reactions, are radically reduced. And the preliminary data, as far as I understand, was presented in December 1998 to the FDA and they just asked for larger numbers to allow us to change the route. And that also helped women in terms of the large local reactions.

And then, the other issue is that we would like to address that fact that in the female population are probably going to be more what we call hyper-responders. And in other vaccine models we know that hyper-responders do not need the full series. And in many vaccine models over time, tetanus was an example, many of you may remember we used to get a booster every 3 to 5 years, now we get it every 10 because it was learned that it wasn't necessary because there was such a high rate of hyper-response as you continue.

And I think we are learning the same lessons with anthrax and that the program will evolve in that knowledge-base to make it better.

Ms. SCHAKOWSKY. I think it is so important that we do carefully examine this data because it is only in recent history that we have even looked at the different impacts on women in clinical trials. For years, only men were observed. And so I think it so important that we don't have a one size fits all when it comes to gender and the application of this vaccine.

Gen. CLAYPOOL. And I believe in the license applications too—excuse me—but I don't think that women were part of the study when the initial license request was submitted. So that is a valid thing that we are pursuing.

Ms. ELLENBERG. I actually—because we don't have the data on gender from the original study, nobody knows for sure, but there are suggestions in the data that women were in fact included. But I would have no idea what the ration was.

These were done in millworkers, and there is no reason to think that there wouldn't have been women.

Ms. SCHAKOWSKY. I am trying to remember what my final—oh, I know what it was. OK, I got it.

I don't know what you call it again, that information sheet that is included with any vaccine.

Col. GERBER. Product insert.

Ms. SCHAKOWSKY. The product insert, were you saying—was it Mr. Chan or Dr. Sharma—that it was based on a different formulation? Is that legal? Are we allowed to do that, to put information about a different drug in, you know?

Mr. SHARMA. I think I am not a lawyer and nor is Mr. Chan, but perhaps the FDA could comment on that. However, to be fair, I think there was an assumption made that these are two very similar vaccines. However, there is a difference between look-alike and having the same gene. They are not identical, and we do know, for example, there are some differences, some of them. Certainly there is some suggestion from the clinical literature that they are associated with higher reactogenicity levels.

One of them is that this vaccine has higher PA content, and there is some suggestion from the different vaccines using different PA content level that higher content levels are associated with higher reactogenicity, for example.

Second, this vaccine uses aluminum hydroxides, and there is some suggestion that similar vaccines, other vaccines, that use aluminum hydroxides have higher reactogenicity. I think these are important differences which I am not sure, and again we are going back to the history, to what extent they were looked or not looked. We have, you know, documentation of the IND that was submitted and any written documentation that existed, which is not much compared to the current standard. So it is really hard to go back and say why they made that assumption, but it is very clear they made an assumption, and everything that we know about what is mentioned there is about from the other vaccine, which was similar.

Ms. SCHAKOWSKY. It just seems to me, in terms of confidence in the entire program, that it is really important that accurate information be given, that there is good access to information, that we monitor accurately and fully inform, and that we process it well. And in that regard, I feel the hearings that I have been at that I don't have that sense of confidence that really any of those things happened.

Col. ENGLER. I would just like to add one comment to what you just said that I think risk communication and communicating with patients at a level that they can understand and that is meaningful for what they experience following any therapy is a continuing challenge for the health-care system in and outside of the military. The CDC has for the standard vaccines, not the travel vaccines, a whole staff dedicated to translating what we call vaccine information sheets cause the package inserts aren't real helpful to patients.

And we are in the process, actually, right now of having a draft document that is being reworked by the CDC to have the same kind of equivalent information as we give to parents of children who are coming for their polio or DPT that is a more balanced reflection of risk communication. And I think we all here recognize that there is a need for improvement in risk communication.

And I think, like with the Lyme vaccine, there is no VIS yes, vaccine information sheet. So we are challenged in the clinical arena

to make our own. And I personally think that before a vaccine is licensed, not just a package insert but a VIS should be developed and marketed with it because right now the clinicians are left a little bit to hang out to dry.

Mr. SHARMA. I think I would like to have a comment to follow Dr. Engler. I think she mentioned about the management strategies that are available for other vaccines, and I think DOD has an opportunity to develop such strategies, especially as they pertain to women, especially as they pertain to people who are hyper-responders. And I think we could really, you know, learn something about this vaccine as it, you know, the events are taking place.

But without those models, it is going to be very difficult to know what is happening to people and something that we have learned, I mean, people call us. Immediately after we started the study we were getting about 100 calls a week between Mr. Chan and myself. And these were calling from public telephones because they were afraid, they didn't want to be identified talking to us.

They see people there left and right are getting sick. Now, it may be, you know, whatever, I am not questioning whether those events were associated with vaccines or not, but they want to be heard, they want to be managed, and such strategies would certainly help gaining confidence of these individuals.

And DOD should consider using or developing models for anthrax as they exist for other vaccines.

Mr. SHAYS. I think we can conclude here by just two questions, and I would like to make an observation, and you might as well. But the first question would be, on what basis, and this would be to you, General Claypool, and others respond, on what basis does the anthrax vaccine immunization program can deploy troops or protect them from anthrax attack after two or three shots when the FDA-approved regimen calls for six.

Gen. CLAYPOOL. We do believe that there is at least evidence to suggest that there is some immunologic protection afforded after two or three shots, but the issue is, is that would we wait until they are fully immunized with six shots before we deploy them. No.

We can't wait until, indeed, you know, a full force totally immunized back within the continental United States before we send them to theaters where there are.

So, we understand that they are not fully protected, but we have started on our road for total force immunization, and that speaks to the issue as to why the whole force has to be immunized because of the fact that we don't have a short lead time. We need a long time to get the force immunized. So that is why we are doing it.

Mr. SHAYS. Does Dr. Engler—excuse me, not Dr. Engler—Dr. Ellenberg, if you would—I used to have a girlfriend named Ellen, that is what is confusing me. [Laughter.]

Dr. Ellenberg, if you——

Ms. SCHAKOWSKY. Too much information. [Laughter.]

Mr. SHAYS. And that can be off the record too. [Laughter.]

Mr. SHAYS. It was legitimate. It was before—many years ago. [Laughter.]

Dr. Ellenberg, would you confirm that there is indication that two or three shots is going to provide protection?

Ms. ELLENBERG. I don't have the numbers from that study in front of me. The vast number of people who—I mean, all the numbers were relatively small—but the big majority of people who did get anthrax in that study were people who did not get any vaccinations. There were a few who were partially vaccinated who also got anthrax, and none with the full vaccination.

Now, I don't have the numbers in front of me to remember there were in each group, that is, how many got the full series, how many got partial. So I can't really—I would have to check that.

Gen. CLAYPOOL. I didn't mean to imply that I think they are fully immunized. In fact, you know, we deploy people after they have one shot if they are going to a theater to start, so——

Mr. SHAYS. I know that. I know that.

Adm. COWAN. As a matter of fact, if I could share—well there is some evidence, going back to the Brachman study, that there is at least partial immunization. It is not our goal, and we feel that we are running somewhat of risk, and we just don't like doing this. But it is an interim measure that we have taken as we go to the total force. When we get to the end of the program, people will come in as a condition of employment, and then we won't have to do things like this.

Mr. SHAYS. Yes, I hear you. What adverse reaction rate would be too high? There must be some level in which we say, it just isn't worth it.

Do we have any documents or memos or anything that have tried to wrestle with this problem?

Gen. CLAYPOOL. I think in part, it would have to be on what kind of an adverse reaction rate it would be and how long it would last, for instance, if indeed we found *X* percent had developed a significant neurologic problem that wound up in paralysis, of course, that would obviously be the case.

I don't mean to be vague. We don't really have an answer.

Mr. SHAYS. That's fair. I think of Captain Piel, and she wants to fly. And one of the things I hope is that we all can find a way to get her healthy again so she can fly.

And, she is a casualty cause she can't—she can still serve, but she can't serve the way she was trained.

Let me ask if any of you would like to just make a closing statement or just an observation or something that you think would contribute to the hearing or you just think you would like to put on the record.

We will start with you, Mr. Chan.

Mr. CHAN. Well, I think as you said, this is the third or fourth hearing you have on this subject.

Mr. SHAYS. Fourth.

Mr. CHAN. Fourth, I'm sorry.

I would like to make one observation. It seems to me that if there is a way for us to all agree with the data, the information that is being given out, being transmitted, being told to the soldiers are in fact of consistent and reliable nature. That, you know, to implement this program, I think partly requires a lot of effort in terms of outreach and people who can speak to the soldiers because, as Dr. Sharma said, we have been partially the receiving end of a lot of phone calls. And we understand a few of their pains.

And we cannot advise them anything further than go to the VAERS system and report, and if they don't want to, we couldn't force them. And as a result, I think, you know, the discussion around the new vaccine needs to be clarified, if that is important or not. The discussion about how do we get to where we are in terms of the early Brachman study using a different formulation basically showing cutaneous anthrax as the vaccine for that particular disease, and then applying it to inhalation anthrax, which is currently what we believe to be a threat, we are using a different formulation, using different strains.

The idea of the fact that the current vaccine may not be as efficacious against other strains in animal studies. The fact that there are potentially concerns about reactions and reactivities, and the differences among sexes, and all those things.

It seems to me that we clarify a lot of things, because this is really not a question of policy, what's important, but rather, how would you implement this program in such a way that in fact would not affect the readiness of our forces. And that is where, you know, I think it is a greater concern than the issue of the details.

Mr. SHAYS. OK. Thank you. Dr. Sharma.

Mr. SHARMA. No. I will pass.

Mr. SHAYS. General Claypool.

Gen. CLAYPOOL. I do have a couple of comments I would just like to make for the record, for that terminology. First has to do with what we were discussing about vaccine immunization indemnification. And, as I understand it and I am not an attorney, of course, but as I understand it, the language that is very commonly used in such indemnification talks about an unusually hazardous risk.

Mr. SHAYS. Yes.

Gen. CLAYPOOL. That unusually hazardous risk should be construed that it is a risk because of medical consequences of the vaccine. It is because of the financial risk to the company, for whom the government is providing indemnification. And it is done, I think, in sisterhood or partnership with the National Childhood Vaccination Injury Act that led to——

Mr. SHAYS. So, in fairness to the military, the terminology is more the legalistic term that is somewhat of a boilerplate. That is your point?

Gen. CLAYPOOL. I believe the ''unusually hazardous risk,'' as I say, is not from the vaccine, per se, but toward the financial risk.

Mr. SHAYS. OK.

Gen. CLAYPOOL. That's the intent behind it. So, when the Secretary of the Army talks about that, he is not talking about the unusual risk from the vaccine.

Mr. SHAYS. OK. Fair enough.

Gen. CLAYPOOL. And No. 2 is, just to make an observation, and that is, and we have talked about this, but it certainly is important to evaluate all these individuals that are here and the ones that are in Dover and the ones that are coming into the Walter Reed clinic, but we ought not assume that there is, necessarily, a cause and effect.

These individuals are ill and they need to have their medical conditions rendered, but the fact that it occurred temporally with rela-

tionship of the vaccine doesn't necessarily make it a fact that it is due to the vaccine.

Mr. SHAYS. I think that is true, but, you know, if in doubt you err on their side.

Gen. CLAYPOOL. Well, the thing we want to do is get them well again and get them back in the cockpit. That is what we want to do.

The third is, you asked us to provide a list of immunologists, and we are certainly happy to do that. I just wanted to hope that you don't assume that—because it will be a low number. Dr. Engler told me that within the Army I think there are like roughly on the order of magnitude of 20 or so immunologists.

You don't need immunologists to take care of people like this. You need immunologists to help direct research and look at laboratory studies and that sort of thing. So, the important thing, I think, is that we have the right specialty and the right mix and the right mechanisms to take care of individuals who are ill. And that will include immunologists, and we will provide that number for you.

The last thing is I think—not last thing, one more thing—is that there is ongoing research, and we can get, if you want, numbers and specificity, but there is ongoing research on two accounts that we talked about. No. 1 is the characterization of the current vaccine, from the standpoint of the antigen that is there, the protective antigen, the concentration, as well as the other antigens that are part of it. So we are looking at, this is the current vaccine.

And second, there is also ongoing characterization of a surrogate animal model. That is how we are going to have to do business in the future anyway with the FDA. We are going to have to do it with surrogate models. That research is under way and ongoing.

Mr. SHAYS. Let me just say, as a courtesy to people when they close, I like not to generally jump in, but on this one I just want to say, I know the military, when they put their mind to it. So on this level here, I think we are pretty much in a kind of a treading water position, and I think you all need to determine where you are going to go.

But I don't have any comfort level that we are pursuing a new vaccine and that this is on a fast track. I don't even think it is on a slow track.

That's with all due respect, but your point is, it's there to be considered and to be pursued and some element of progress is being made.

Can we agree on that?

Gen. CLAYPOOL. Yes. I was trying to address more specifically the GAO's talk about looking at surrogate models. We are doing that. We are working on it.

And last, I really do appreciate, sir, the opportunity to come before you. I am very, I am very much committed to this program. I really do believe that the risk is real and that we have a safe and effective vaccine when——

Mr. SHAYS. Just to clarify for the record: the risk of an enemy using anthrax.

Gen. CLAYPOOL. Yes. And I think that the product that we have has a profile of adverse events that is comparable to other vaccines.

We are continuing to look for this, for anymore severe reactions, but I think it is the right program for the country at this time.

Mr. SHAYS. Thank you.

Adm. COWAN. Sir, I am also grateful for the opportunity to be here and speak. The only job I have ever held in my entire adult life has been a Navy doctor, taking care of sailors and Marines, and now being responsible for the other services too.

I am particularly grateful, and I feel obligated to comment about the first panel, not only for their courage to stand up, but my dismay that they had to have that courage, my dismay that the leadership somehow stiff-arms people and that the medical department pushes them away or makes access to care difficult.

And, frankly, that just, I find that, I don't know, equal parts, saddening and infuriating. And one of the major messages that I go back with is my eyes opened up at our continuing problem of getting our people in to do the right things for them.

So I thank you very much for that, sir.

Mr. SHAYS. Thank you. Thank you for those comments.

Yes, sir, Colonel Gerber.

Col. GERBER. Sir, I was also struck, impressed with your opening premise that we are all interested in the safety and welfare of our service members, and I think you can assume—I mean, that is job No. 1, that is what we do for a living. I have been associated with the anthrax vaccine immunization program everyday for the past 20 months. And the easiest part of my job is accepting the national intelligence estimates that are validated every year by the five war-fighting CINC's that readily, beyond any reasonable doubt, depict an array of anthrax weaponized threat arrayed against our servicemen.

The second part of my job is my overwhelming belief in the safety and efficacy of an FDA-certified vaccine that we know is safe, it's effective, just as safe, and as reactogenic as many of the national vaccines that we employ.

So, thank you very much for this opportunity.

Mr. SHAYS. Thank you very much. Colonel Engler.

Col. ENGLER. I also would like to thank the committee for the opportunity to participate, and for me, at least, a unique experience. I would like to also, for the record, state that I think the anthrax program and the lessons learned as we evolve it are very important lessons that may someday have value added for the taxpayers' money expended in a future flu pandemic.

As the ex-officio member to the National Vaccine Advisory Committee, I think there is a serious concern of how do you deliver a vaccine rapidly and effectively to millions of people to save lives. And a flu pandemic in the future, where in months we can see millions of people die, is an awesome thought. And how we, as a military, will play in that, some of the lessons learned from this program may add value to that experience.

Mr. SHAYS. Thank you. Ms. Ellenberg, doctor.

Ms. ELLENBERG. I would just like to say that we have made, and will continue to make, the review of the VAERS reports on anthrax a high priority. And we expect and are happy to continue working with the DOD to enhance the effectiveness of the reporting programs.

Mr. SHAYS. Thank you. Dr. Braun, would you like to make a comment.

Dr. BRAUN. Thank you for the opportunity. I have no comment to make right now.

Mr. SHAYS. Well, it has been a very helpful hearing. This committee wants to weigh in on the right side, and we, I think, we have some sense of where we want to move, but it is a gigantic issue. The threat, the terrorist threat is real, the threat that our adversaries may use chemical or biological or even nuclear weapons to work their will is very real. Terrorist threats are extraordinarily real. So, this is a big deal.

Thank you very much.

And, my colleague, any comments you would like to make.

Ms. SCHAKOWSKY. Let me just say, for my part, in closing that in our understandable zeal to protect our service men and women from the threat of anthrax and ultimately to protect all Americans, therefore, what I don't want to see happen is that we are willing to sacrifice good science, good medicine, good production methods, and, ultimately, the good treatment of those individuals who truly want to serve their country.

Mr. SHAYS. We will conclude by thanking the majority and minority staff for their good work, as always, and particularly, on bended knee, to thank our court reporter, Ron Claxton, who is, who I am at his mercy. [Laughter.]

We will now adjourn. [Laughter.]

[Whereupon, at 3:07 p.m., the subcommittee was adjourned.]

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